Trials

STUDY PROTOCOL

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Therapeutic exercise protocol for the prevention of anterior cruciate ligament injuries in female soccer players with dynamic knee valgus (RCT)

Amanda Coves García[1*] and Emilio José Poveda Pagán[2,3]

Abstract

Background Women's football has experienced exponential growth over the last 10 years. Its popularity is associated with an increase in ACL injuries. They constitute a major current problem as they account for 43% of the injury burden during the sports season. Despite the existing training programs, 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 the current programs.

Methods Randomized, double-blind, single-center clinical trial protocol scheduled for the 2025–2026 women's football season. There will be 2 groups: a group that will follow a specific ACL injury prevention protocol and a control group. The intervention period will last 12 weeks. Measurements will be taken at 3 time points. The biomechanics of the lower limbs, the jump-landing dynamics, and the pre- and post-training satisfaction of the players will be evaluated. Image capture and processing systems will be used as well as tests such as the DVJ and the LESS scoring system, among others.

Discussion This protocol aims to be one of the first to implement an ACL injury prevention program for women footballers with DKV. Despite the scarcity of research in this area, studies support beneficial effects at a preventive level.

Trial registration ClinicalTrials.gov NCT06083818. Registered on 03 October 2023.

Keywords Anterior cruciate ligament injuries, Knee trauma, Knee joint, Female, Football

Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

Title{1}	Therapeutic exercise protocol for the prevention of anterior cruciate ligament injuries in female soccer players with dynamic knee valgus (RCT).

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Trial registration {2a and 2b}.	ClinicalTrials.gov Protocol Record 04122022 ClinicalTrials.gov Identifier: NCT06083818 Registered 03 October 2023
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Funding {4}	Financial support from the Physiotherapy clinics in Alicante
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Role of sponsor {5c}	Organization of the study and the steps to be carried out by each professional involved in this protocol

Introduction

Background and rationale {6a}

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 are 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 kinematics [2]. It stabilizes the joint in full extension and prevents rotational loads and anterior displacement of the tibia [3]. 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 season [6]. Regardless of their level of participation, female footballers have between 2 and 8 times [7] times the risk of suffering ACL injuries compared to their male counterparts [5] performing similar training [8–10]. Injury incidence rates among female soccer players range from 1.1 to 3.1 injuries per 1000 h of training and from 12.6 to 23.6 injuries per 1000 h of play over the past decade [1].

Most ACL injuries among female players occur without contact from another player [5]. 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 chain [15] (ACL weakness, generalized tibiofemoral laxity, narrow intercondylar grimace, 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 slowdown [5]. 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] suggest 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 patterns [21] in muscle co-contraction actions [22], greater degrees of ankle eversion, asymmetric landings, and poor ability to control the trunk [7] 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 factor [24] 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, hip adduction, and knee abduction, in addition to distal joint modifications such as anterior translation, 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 more [6], which can mean the premature end of the player due to a decrease in her sports performance [2]. These injuries can cause significant morbidities in the short and long term, highlighting chronic knee instability, persistent knee pain [30], 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 term [31]. 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 propose, as a continuation of the current research process, an exercise protocol, as well as its dosage [37], to a group of female soccer players with DKV. On the other hand, as we want to check if the benefits are greater following this protocol, that is, if there is a reduction in the risk of ACL injuries, we need to compare it with a control group that continues with their usual training.

Objectives {7}

Main objective

The main objective is 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 2025–2026 season will significantly reduce the risk of ACL injuries compared to conventional training for female soccer players with DKV.

Trial design {8}

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 guide [36] have been followed for the realization of this study (Annex I) (Fig. 1).

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 in order to verify whether this specific protocol produces benefits superior to conventional sports training. This study will consist of 3 time measurement points, the first prior to the intervention, the second at the end

	STUDY PERIOD							
	Enrolment	Allocation	Post-allocation					Close-out
TIMEPOINT**	$-t_1$	0	t_1	t_2	t_3	t_4	etc.	t_x
ENROLMENT:								
Eligibility screen	X							
Informed consent	X							
[List other procedures]	X							
Allocation		X						
INTERVENTIONS:								
[Intervention A]			←	—	→			
[Intervention B]			X		X			
[List other study groups]			←	—	—	→		
ASSESSMENTS:								
[List baseline variables]	X	X						
[List outcome variables]				X		X	etc.	X
[List other data variables]			X	X	X	X	etc.	X

Intervention A = ACL protocol
Intervention B = control group

Fig. 1 SPIRIT figure

of the 6-week period of intervention, and the last at 6 months after its completion. The study schedule and flowchart are in Annex III and IV, respectively.

Methods: participants, interventions, and outcomes

Study setting {9}

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 2025–2026 season, where three weekly training sessions of 1 h each are carried out.

Eligibility criteria {10}

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 1 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 6 months prior to the study.
- Players with chronic illnesses that may affect test results (rheumatic or neurological diseases)
- Subjects who practice other sports in the professional field.

Who will take informed consent? {26a}

Prior to the start of the study, the physiotherapist responsible for the protocol will provide informed consent to each of the players and collect it in a sealed envelope.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

This study does not require additional consent for the collection and use of data and biological samples from the participants of ancillary studies.

Interventions

Explanation for the choice of comparators {6b}

These two teams will be chosen because of their proximity to the area where the study will be carried out and because they are two teams that record a large number of knee injuries and, specifically, ACL injuries.

Intervention description {11a}

First, an invitation will be made to all the players who are part of the teams mentioned above during the 2025–2026 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, 3 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 1 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 h 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 min 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 program will be organized into three phases of implementation:

The exercises integrated into the program will be organized 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 imputs 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.

Criteria for discontinuing or modifying allocated interventions {11b}

The trial may be interrupted at the request of each participating subject due to the appearance of pain or injury during the intervention. On the other hand, an Excel table will be used to record the number of injuries produced, among the players who remain in both groups until the end of the study, and the weekly training frequency.

Strategies to improve adherence to interventions {11c}

To improve adherence to the exercise program, each participant will complete an exercise diary during the intervention process in order to analyze the progress of each participant [39, 40, 41].

Relevant concomitant care permitted or prohibited during the trial {11d}

The players will be asked to refrain from consuming performance stimulants, tobacco or alcohol, non-steroidal anti-inflammatory drugs (NSAIDs), or analgesics 24 h before each session, as well as strenuous exercise.

Provisions for post-trial care {30}

The protocol does not involve any risks for participants beyond the sporting practice that is not a part of it, since it involves controlled exercises and no dangerous interventions are applied.

Outcomes {12}

The main outcome we expect to obtain from the intervention group is to reduce the incidence of any ACL injury during the application of a specific and comprehensive training protocol focused on players with DKV by recording the presence/absence of injury 6 months after the end of the intervention. Moreover, we expect to obtain a modification of risk factors such as the one mentioned above (DKV) and 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 (gluteus maximus and medius of both lower limbs) will be collected and processed with an EMG system [19, 27, 29, 30]. This system will record the maximum contraction of the mentioned muscles in percentages. 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.

Participant timeline {13}

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 6 months

after its completion. The study schedule and flowchart are in Annex III and IV, respectively.

Sample size {14}

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).

Recruitment {15}

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, such as an interview, with the coach, the physiotherapist, and the physical trainer of the participating teams.

Assignment of interventions: allocation

Sequence generation {16a}

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. The randomization method will consist of the toss of a coin assigning "heads" to the intervention group and "tails" to the control group.

Concealment mechanism {16b}

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.

Implementation {16c}

Group assignments will be performed by a person independent of the study. The study will have two physiotherapist evaluators, with at least 5 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 5 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.

Assignment of interventions: blinding

Who will be blinded {17a}

The professionals who will be blinded will be the assessing physiotherapists and the footballers from both study groups. The only professionals who will not be blinded are the sports physiotherapists.

Procedure for unblinding if needed {17b}

Our process avoids by which the identifying information for our patient or group of outcomes from our clinical trial is revealed to the subject and/or investigators conducting the study.

Data collection and management

Plans for assessment and collection of outcomes {18a}

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 questionnaire [38] (Annex VI).

Plans to promote participant retention and complete follow-up {18b}

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 6 months after its completion. The study schedule and flowchart are in Annex III and IV, respectively. To promote participant retention and complete follow-up, we have an exercise diary to aid adherence as well as the use of the EARS scale [42]. In addition, we count on the commitment of the trainers and physical trainers to ensure that it can be carried out in the most correct way possible.

Data management {19}

To manage the data obtained, they will be coded with numbers to anonymize the subjects of the study.

Confidentiality {27}

A number will be assigned to each study participant in addition to anonymizing the data from each of the interventions performed.

Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Such samples are not collected.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

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 (the 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.

Interim analyses {21b}

The one who will have access to the intermediate results and who will make the final decision to terminate the trial will be the principal investigator.

Methods for additional analyses (e.g., subgroup analyses) {20b}

It does not require additional statistical analysis.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

To avoid non-compliance with the protocol, the sample will be increased by 10%, but if there is still evidence of non-adherence to the protocol, the intention to treat principle will be applied and in the case of missing data, the multiple imputation principle will be followed.

Plans to give access to the full protocol, participant-level data, and statistical code {31c}

The protocol will be accessible through the journal and the data must be requested from the corresponding author of the article.

Oversight and monitoring

Composition of the coordinating center and trial steering committee {5d}

There is no steering committee or management or oversight team other than the lead author and protocol contributor.

Composition of the data monitoring committee, its role and reporting structure {21a}

This type of ACL injury prevention study does not require a data monitoring committee because what we are looking for is to know the incidence of ACL injuries.

Adverse event reporting and harms {22}

For the collection, assessment, reporting, and management of requested and self-reported adverse events and other unwanted effects of interventions or trial conduct, adapted Excel templates will be used in which percentages of asymmetry at the EMG level greater than 15% will be collected and abnormal VAS changes greater than 3 will be collected.

Frequency and plans for auditing trial conduct {23}

The protocol will have a timetable for its execution and as the items are carried out they will be marked in a checklist.

Plans for communicating important protocol amendments to relevant parties (e.g., trial participants, ethical committees) {25}

Important modifications to the protocol will be communicated via WhatsApp notifications.

Dissemination plans {31a}

The aim of this work is to be published in this journal. In addition, once published, the results will be disseminated through social networks and via email to the participants.

Discussion

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 training

[14]. 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 exercises [11].

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.

Trial status

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Miguel Hernandez University of Elche Protocol Record 04122022.

Number version: TRLS-D-23–01291. October 2023.

Date recruitment starts/finish: September – October 2025.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-025-08736-7.

Supplementary Material 1. Annex I: SPIRIT checklist. Annex II: Informed consent form for study participation. Annex III: Timeline. Annex IV: Flow chart. Annex V: Landing error system LESS. Annex VI: SF-12 scale. Annex VII: Calculation of the sample size. Annex VIII: DVJ Test. Annex IX: Programming intervention protocol. Annex X: Infographic action protocol for women's football coaches.

Acknowledgements
Not applicable.

Authors' contributions {31b}
Coves García, Amanda is the principal investigator, conceived and designed the study, led and developed the proposal and protocol, and was the main methodologist of the trial. The final manuscript was read and reviewed by Poveda Pagán, Emilio José.

Funding {4}
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 (€ 5500 approx.) and the BMS force platform (€ 3000 approx.) should be included in the budget.

Data availability {29}
The final test dataset will be accessible to all readers after publication in this journal.

Declarations

Ethics approval and consent to participate {24}
Responsible Research Code: TFM.MFA.EJPP.ACG.230330.
ClinicalTrials.gov Identifier: NCT06083818.

Consent for publication {32}
The informed consent form is attached in the annexes section.

Competing interests {28}
The authors declare that they have no financial or personal relationships with other individuals or organizations that could inappropriately influence their work.

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