ANNEXES AND ICF

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

Annex I: SPIRIT checklist

Table 1 | SPIRIT 2013 checklist: recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
	6b	Explanation for choice of comparators
Objectives	7	Specific objectives or hypotheses
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see fig 1)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
Methods: Assignment of interventions (for controlled trials)		
Allocation:		
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts) and how
	17b	If blinded, circumstances under which unblinding is permissible and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*Amendments to the protocol should be tracked and dated. The SPIRIT checklist belongs to the SPIRIT Group and is reproduced by BMJ with their permission

BMJ: first published as 10.1136/bmj.e7586 on 9 January 2013.

Annex II: Informed consent form for study participation

VALENCIAN GENERALITAT
Ministry of Universal Health and Public Health

SPECIALTY

PROCEDURE NAME

DECLARATION OF INFORMATION AND CONSENT

PATIENT DATA

SURNAMES	NAME	ID	BIRTHDATE

Nº SIP	ADDRESS (STREET/SQUARE, NUMBER AND DOOR)	PC

LOCATION	PROVINCE	PHONE	EMAIL

DATA OF LEGAL REPRESENTATIVE

SURNAMES	NAME	DNI	BIRTH DATE	AS

PROFESSIONAL DATA

SURNAMES	NAME	PROFESSIONAL CATEGORY	NUM. COLLEGE

I declare that:
-It has been explained to me that it is convenient/necessary to carry out this procedure -I have understood the information received
-I have been able to ask all the questions that I thought appropriate
- I have been informed that I can revoke my consent at any time.

Therefore:

☐ I authorize the performance of this procedure ☐ I do not authorize the performance of this procedure

_____, _____ of _____ of _____

Patient / his representative. healthcare professional

Signature: _____ Signature: _____

REVOCATION OF THE DECLARATION OF INFORMATION AND CONSENT

I revoke the consent given on the indicated date

_____ _____ of _____ of _____

Patient / his representative. healthcare professional

Signature: _____ Signature: _____

WAIVER OF RIGHT TO INFORMATION

I declare that for personal reasons, I waive the right to information that corresponds to me as a patient and I express my desire not to receive information, at the present time, about the process of my disease without implying that I cannot give my consent to undergo this intervention, as I have provided and signed in the previous section.

_____, _____ of _____ of _____

Patient / his representative. healthcare professional

Signature: _____ Signature: _____

USE OF IMAGES AND VIDEOS FOR SCIENTIFIC PURPOSES

I have been informed that the procedure can be recorded and the data used for scientific and/or educational purposes, always ensuring my privacy and anonymity. Thus:

I AUTHORIZE: ☐ I DO NOT AUTHORIZE: ☐

Patient / his representative: Health professional:

Signature: _____ Signature: _____

REVOCATION OF THE USE OF IMAGES AND VIDEOS FOR SCIENTIFIC PURPOSES

I revoke the Consent given on the indicated date:

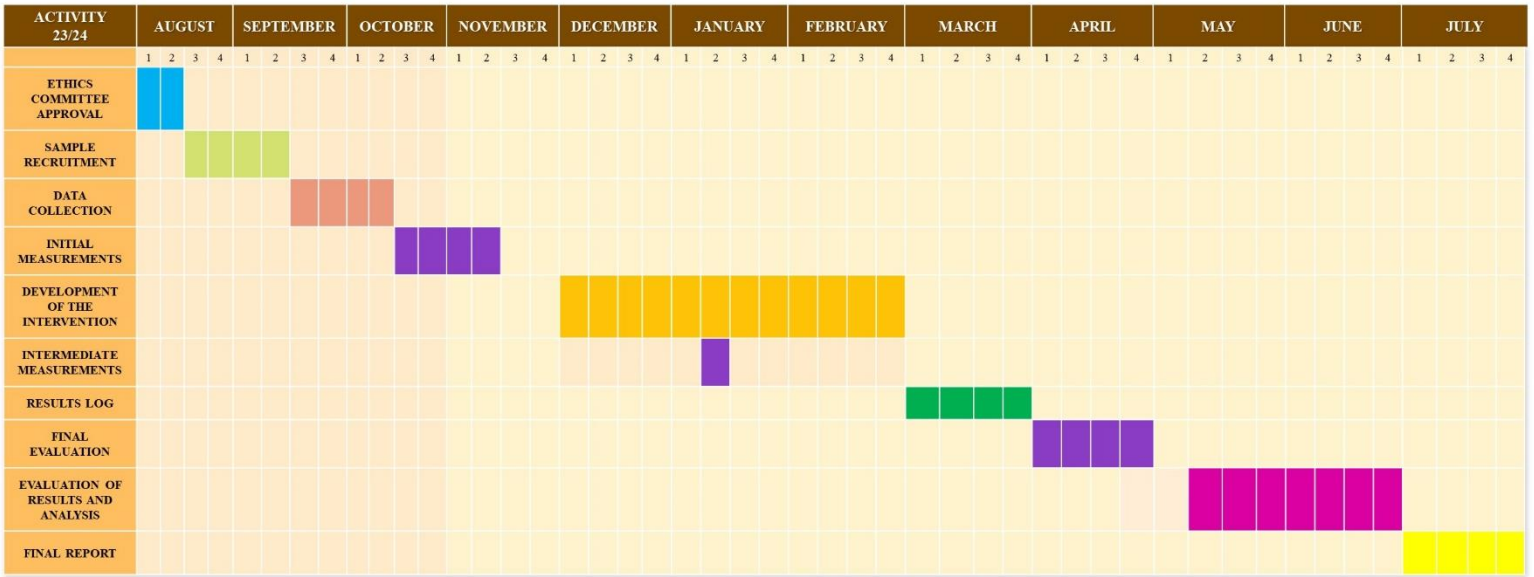
Patient / his representative: Health Professional:

Signature: _____ Signature: _____

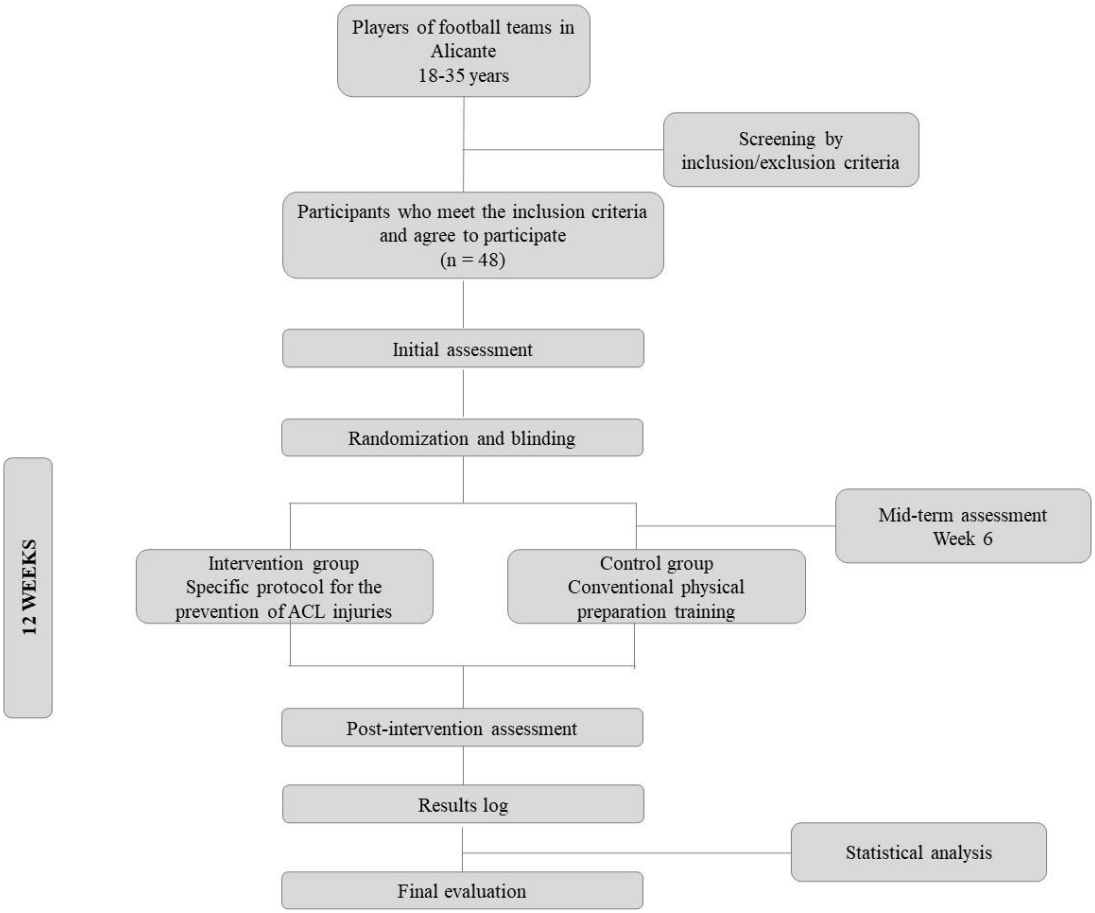
In the event of non-coexistence of the spouses with shared parental authority, the father and mother must sign, otherwise the parent

who holds it Personal data will be processed in accordance with Organic Law 3/2018, of December 5, Protection of Personal Data 1 and guarantee of digital rights

Annex III: Timeline



Annex IV: Flow chart



Annex V: Landing error system LESS

LANDING ERROR SCORING SYSTEM (LESS)

SAGGITAL VIEW:	Check if an error: 1	2	3
1. Knee Flexion Angle at Initial Contact: **> 30 deg.** **Error if NO**	☐	☐	☐
2. Hip Flexion Angle at Initial Contact: **Hips are Flexed** **Error if NO**	☐	☐	☐
3. Trunk Flexion Angle at Initial Contact: **Trunk is Flexed** **Error if NO**	☐	☐	☐
4. Knee Flexion Displacement: **> 45 deg. more than Initial Contact** **Error if NO**	☐	☐	☐
5. Hip Flexion Displacement: **Hips flex more than Initial Contact** **Error if NO**	☐	☐	☐
6. Trunk Flexion Displacement: **Trunk flexes more than Initial Contact** **Error if NO**	☐	☐	☐
7. Ankle Plantar-Flexion Angle at Initial Contact: **Toe to heel** **Error if NO**	☐	☐	☐
FRONTAL VIEW:			
8. Initial Foot Contact: **Symmetrical** **Error if NO**	☐	☐	☐
9. Lateral Trunk Flexion at Initial Contact: **Trunk is Vertical** **Error if NO**	☐	☐	☐
10. Knee Valgus Angle at Initial Contact: **Knees over mid foot** **Error if NO**	☐	☐	☐
11. Stance Width: **< Shoulder width** **Error if YES**	☐	☐	☐
12. Stance Width: **> Shoulder width** **Error if YES**	☐	☐	☐
13. Max IR Foot Position: **Toes > 30 deg. IR at max flexion** **Error if YES**	☐	☐	☐
14. Max ER Foot Position: **Toes > 30 deg. ER at max flexion** **Error if YES**	☐	☐	☐
15. Knee Valgus Displacement: **Medial knee movement at max flexion** **Error if YES** **(Tibial tubercle inside 1st ray)**	☐	☐	☐
OVERALL:			
16. **Joint Displacement (Sagittal Plane)** **SOFT = no error, AVERAGE = 1 error, STIFF = 2 errors**	☐	☐	☐
17. **Overall Impression** **EXCELLENT = no error, AVERAGE = 1 error, POOR = 2 errors**	☐	☐	☐
TOTALS:	_____	_____	_____ **AVG:** _____

Annex VI: SF-12 scale

I.M.P.R.E.S.S.

SF-12v2™ Health Survey

(SF-12 v2 Standard, US Spanish Version 2.0)

To be completed by the PATIENT

(For Internal Use Only)

Patient Study Number	Completed By:_____ Clinic:_____
Visit Date (MM/DD/YY) __ __ / __ __ / __ __	Visit Schedule *(check appropriate box)* ☐ Preop ☐ 3 mo ☐ 6 mo ☐ 12 mo ☐ 24 mo

INSTRUCTIONS: The questions that follow ask about what you think about your health. Your answers will let us know how you are doing and to what extent you are able to do your usual activities.

Please answer each question by checking one box. If you are not sure how to answer a question, please answer what seems most true to you.

1. In general, would you say that your health is:

☐ Excellent ☐ Very good ☐ Good ☐ **Regular** ☐ Bad

The next questions ask about activities or things that you might do on a normal day. Does your current health limit you from doing those activities or things? If so, how much?

	yes it limits me a lot	Yes, it limits me a little	No, it doesn't limit me much
2. Moderate efforts, such as moving a table, vacuuming, bowling, or walking for more than 1 hour	☐	☐	☐
3. Climb several floors up the stairs	☐	☐	☐

During the last 4 weeks, have you had any of the following problems at work or in your daily activities, due to your physical health?

	Yes	No
4. Did you do less than you wanted to?	☐	☐
5. Did you have to stop doing some tasks at work or in your daily activities?	☐	☐

I.M.P.R.E.S.S.

SF-12v2™ Health Survey

(SF-12 v2 Standard, US Spanish Version 2.0)

To be completed by the PATIENT

(For Internal Use Only)

Patient Study Number	Completed By:_____ Clinic:_____
Visit Date (MM/DD/YY) ___ ___ / ___ ___ / ___ ___	Visit Schedule *(check appropriate box)* ☐ Preop ☐ 3 mo 6 mo ☐ 12 mo 24 mo

During the last 4 weeks, have you had any of the following problems at work or with your daily activities, because of an emotional problem (such as being sad, depressed, or nervous)?

	Yes	No
6. Did you do less than you would have liked to, because of an emotional problem?	☐	☐
7. Did you not do your work or daily activities as carefully as usual because of a problem? emotional?	☐	☐

8. During the past 4 weeks, to what extent has pain interfered with your usual work (including work outside the home and household chores)?

☐ Nothing ☐ A bit ☐ **Regular** ☐ Quite ☐ A lot

The questions that follow ask about how you have been feeling and how things have been going for you in the last 4 weeks. For each question, answer what is closest to how you felt. During the past 4 weeks, how long...

	Always	Almost always	Many times	Sometimes	only ever	Never
9. Did you feel calm and peaceful?	☐	☐	☐	☐	☐	☐
10. did you have a lot of energy?	☐	☐	☐	☐	☐	☐
11. felt down and sad?	☐	☐	☐	☐	☐	☐

12. During the past 4 weeks, how often have physical health or emotional problems made it difficult for you to do social activities (such as visiting friends or family)?

☐ Always ☐ Almost always ☐ Sometimes ☐ only ever ☐ Never

Annex VII: Calculation of the sample size

[1] Sample sizes. Comparison of independent means:

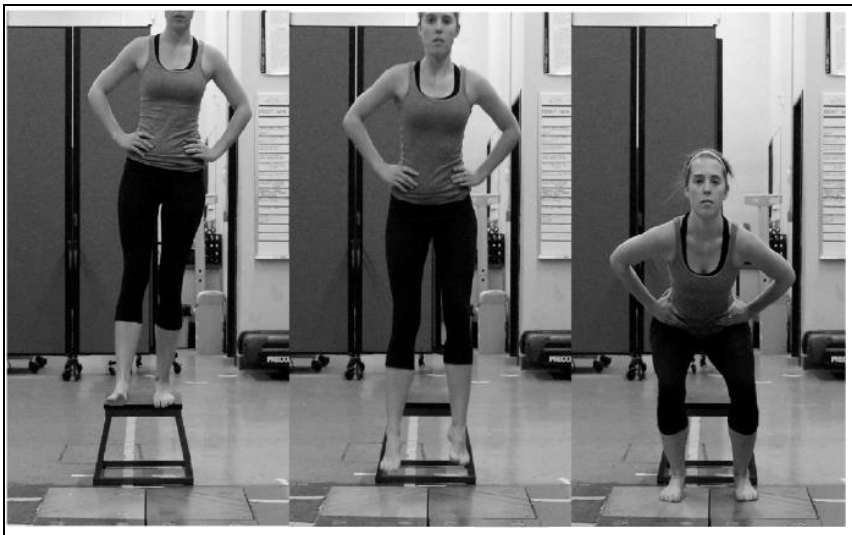
Data:

Variances:	equal
Option:	Option 2
Standardized difference of means:	1,000
Ratio between sample sizes:	1.00
Confidence level:	95.0%

Results:

Power (%)	Sample size		
	Population 1	Population 2	Total
80.0	17	17	34
85.0	19	19	38
90.0	22	22	44
95.0	27	27	54

Annex VIII: DVJ Test



Footballers will be dropped from a box 30 cm high and immediately after landing they will perform a maximum vertical jump and hit on a force plate.

A qualitative and quantitative analysis will be carried out on the players prior to the start of the study to detect DKV and select only those who had it. This test will also be carried out on subsequent measurements to assess possible changes.

Three successful trials of all jumps executed will be recorded.

Qualitative analysis:

0 = no DKV or mid-lateral knee movement and toe alignment.

1 = when there is a slight DKV position of one or both knees.

2 = DKV in at least one knee, its alignment and that of the toes is poor and substantial amount of mean lateral movement of the knee.

Quantitative analysis:

The jump that gets the most points will be considered the worst jump, it will be used in the analysis and to represent the movement pattern of greatest potential risk for the player.

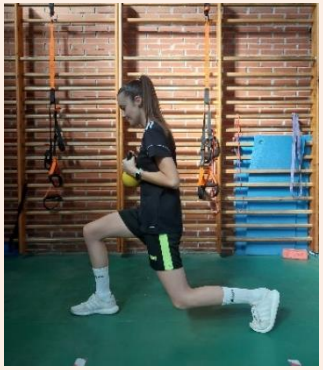
Each jump will be awarded one point based on the following criteria. If your feet:

1. leave the box or land at different times
2. are not parallel when landing or rotate if DKV is present
3. They are not separated approx. at shoulder distance
4. if there is any weight displacement.

Annex IX: Programming intervention protocol

SPECIFIC TRAINING PROTOCOL FOR THE PREVENTION OF ACL INJURIES			
1st PHASE – ADAPTATION	**2nd PHASE – IMPROVEMENT**	**PHASE 3 – PERFORMANCE**	**EXERCISE DESCRIPTION**
BAND WALK (3 x 1') 	BAND HIP THRUST (3 x10) 	SINGLE LEG HIP THRUST (3 x 10) 	It consists of walking with theraband on ankles back and forth, one side and another. **Progression 1**: hip lift with theraband resistance **Progression 2:** hip lift with theraband on knees, knee extension and weight on pelvis
GOBLET SQUAT (3 x 10) 	SQUAT (3 x 10) 	SQUAT JUMP (3 x 10) 	It consists of performing a squat with a weight attached to the chest. **Progression 1**: squat with barbell, do not lower the knees to more than 90º **Progression 2:** same as above + vertical jump. **In the 3 exercises a theraband will be added between the knees*

BOX JUMP (3 x 10) 	DOUBLE LEG DROP JUMP (2 x 10)   	SINGLE LEG DROP JUMP (4 x 6)*   	It consists of making a jump on a 50 cm drawer **Progression 1**: Bounce jump + bipodal maximum vertical jump **Progression 2**: Bounce Jump + Unipodal Maximum Vertical Jump **2 sets with each leg*
SQUAT JUMPS (3 x 10)  	90º VERTICAL JUMP (3 x 10)  	180º JUMPS (3 x 10)  	It consists of making a jump and landing in the same place going down to squat. **Progression 1**: Jump and make a 90º turn **Progression 2:** Jump and make a 180º turn

BAND LUNGE (3 x 10) 	WEIGHT BAND LUNGE (3 x 10) 	JUMP LUNGE (SCISSOR JUMPS) (3 x 10)  	It consists of making an anterior stride, at 45º and 90º (several directions) with theraband. **Progression 1**: multi-direction stride + chest weight + theraband to stabilize knee **Progression 2**: Dynamic strides with weight
STIFF LEG DEADLIFT + BALL GLUTE BRIDGE BOTH KNEES (3 x 10)    	SINGLE LEG DEADLIFT + BALL GLUTE BRIDGE ONE KNEE (3 x10)  	NORDIC HAMSTRINGS (2 x 8)* 	It consists of performing 1st and 3rd series of deadlift with weight and the 2nd gluteal bridge on bipodal fitball performing flexo-extension knees **Progression 1**: deadlift with weight and gluteal bridge on unipodal flex-knee extension fitball **Progression 2**: hamstring eccentric. **1st series with straight body and 2nd series with inclined body. When it passes 45º drop slowly.*

PLANK + SIDE PLANCK (4 x 30’)  	PLANK TO PRESS + PLANK KNEE TO CHEST + PELVIC RETROVERSION AND ANTEVERSION + SIDE PLANK WITH HIP ABDUCTION (4 x 30’)    	SWISS BALL PLANK (6 x 10)  	It consists of making 2 series of plate in prone position and 2 in lateral decubitus position. **Progression 1**: 1st series plate with elbow-hand support + 2nd series knees to the chest + 3rd retro series and pelvic anteversion + 4th series side plate with hip abduction **Progression 2**: 3 sets with elbows on fitball (flex-ext + circles) and 3 sets feet on fitball (flex-ext knees)
BULGARIAN SPLIT SQUAT (3 x 10) 	CROSSOVER HOP-STICK (3 x 10) 	SINGLE LEG CROSSOVER DROP (4 x 6) 	It consists of making a stride and keeping the leg behind on a surface **Progression 1**: unipodal zig-zag jumps **Progression 2:** unipodal cross fall from 50 cm drawer. 2 series with right leg support and 2 others with left leg support

<table>
<tr>
<td>BOSU BOTH KNEES DEEP HOLD- MEDICINE BALL CATCH (3 x 30’)
  </td>
<td>BOSU BOTH KNEES DEEP HOLD – KICK BALL (3 x 30’)
  </td>
<td>LATERAL SQUAT JUMPS OVER THE BOSU (3 x 30’)
  </td>
<td>It consists of maintaining bipodal balance on BOSU while throwing a soccer ball.

Progression 1: keep balance on BOSU unipodal + ball kick with inside leg or head shot

Progression 2: unipodal lateral jump with support on BOSU</td>
</tr>
<tr>
<td>RUSSIAN TWIST + CRUNCHES (6 x 25)
 
  </td>
<td>DOUBLE CRUNCHES (6 x 25)
  </td>
<td>ABDOMINAL ROLLER (4 x 10)
  </td>
<td>It consists of performing 3 sets of abdominals with trunk turns + soccer ball and another 3 series of conventional abdominals

Progression 1: abs with knee flexion + medicine ball between knees

Progression 2: eccentric abdominal exercise with abdominal roller</td>
</tr>
<tr>
<td colspan="4">*In all exercises with weight, you will work with loads between 70-80% of 1RM
* The height of the drawer of the exercises that is required will increase depending on the progression of the athletes, starting with a drawer of 50 cm in height
Photographs taken of a CF Monnegre Mutxamel player, who gave her consent to appear in the photos without pixelating her face</td>
</tr>
</table>

Annex X: Infographic action protocol for women's football coaches