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The preventive effect of an adductor strengthening program on groin problems in Norwegian male football players

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28/01/2016

Recruitment status
No longer recruiting

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29/01/2016

Overall study status
Completed

Last Edited
17/05/2019

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A groin strain happens when you overstretch or tear one of the adductor muscles around the groin. Groin injuries are common in sports involving explosive actions like kicking, cutting, change of directions and rapid acceleration, such as football. Recent studies have shown that previous injuries, higher level of play and reduced hip adductor muscle strength increase the risk of groin injuries. The aim of this study is to investigate whether an adductor strengthening program (ASP) helps prevent groin problems in male football players.

Who can participate?
Male football players playing on the second or third level of senior Norwegian football

What does the study involve?
Participating football teams are randomly allocated to either continue their normal training schedule or take part in an adductor strengthening program (ASP). The ASP is a groin injury prevention program designed to increase hip adductor strength. All players are asked to complete a questionnaire weekly using a smartphone application. Based on the response from the players, each case is categorized as a groin problem, substantial groin problem or no groin problem. We also offer a clinical examination by a groin injury specialist.

What are the possible benefits and risks of participating?
The knowledge gained will be of use to football players, scientists, clinicians (doctors, physical therapists, athletic trainers) and coaching staff working with football players. The adductor strengthening program we plan to use has no known side effects and there is no potential risk involved in participating in the study.

Where is the study run from?
Oslo Sports Trauma Research Center (Norway)

When is the study starting and how long is it expected to run for?
February to November 2016

Who is funding the study?
Oslo Sports Trauma Research Center (Norway)

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The preventive effect of an adductor strengthening program on groin problems in Norwegian male football players: a cluster randomized controlled trial

Acronym
PEASP

Study objectives
A structured strengthening program including only one exercise targeting the hip adductor muscles will reduce the prevalence of all groin problems during a regular football season in players randomized to perform an adductor strengthening program compared to players randomized to act as a control group who follow their regular training schedule.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Regional Committees for Medical Research Ethics, 19/11/2015, case number: 2015/1922/REK South East
2. Norwegian Social Science and Data Service, 27/11/2015, case number: 45388/3/LT/LR

Study design
Multi-team cluster-randomized single-blind controlled trial.

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Groin problems in football players.

Interventions
We will invite 40 teams (N=800) from PostNord-ligaen and OBOS (1. Division, 2nd level and 2. division, 3rd level) in Norwegian football to take part in a cluster-randomized controlled trial in the 2016 season from February through to October to examine the injury preventing effect of an adductor strengthening program (ASP). The teams will be randomized into two different groups, an intervention group (performing the ASP) and a control group performing their regular training program. A statistician at OSTRC will generate a randomization list and an independent third person will allocate group assignment using sealed envelopes. Teams will be randomized to either group once they have accepted the invitation to participate in the project. An independent third person will open the sealed envelope and reveal group assignment.

The players will be asked to download a smartphone application (Spartanova, Ghent, Belgium) and log on with a pre-generated username and password. Players in both groups will be asked to complete the OSTRC Overuse Injury Questionnaire each week. A push notification linking the players to the questionnaire will be sent every Sunday and a reminder push notification on subsequent days to non-responders. The principal investigator will send a SMS reminder Monday and Thursday each week to non-responders. The players will be asked to register training and match exposure. Players in the intervention group will also be asked questions about the number of training sessions performing the ASP.

During February, we will visit each team included in the study, with information regarding the project, registration of The Copenhagen Hip and Groin Outcome Score (HAGOS), demographic data and written consent form. For teams in the intervention group, coaches, physiotherapists and players in each team will be given instructions on how to perform the ASP. The principal investigator will have the main contact with all teams in the intervention group, while eight regional physiotherapists, recruited by OSTRC, will be the main contact for teams in the control group. Throughout the intervention period, both the principal investigator and the regional physiotherapists will visit the teams regularly to maintain motivation among both coaches and players.

OSTRC Overuse Injury Questionnaire
We will use the OSTRC Overuse Injury Questionnaire to register groin problems throughout the 2016 season. The questionnaire consists of four questions, where question one and four have four response alternatives while question two and three have five response alternatives, with severity in parenthesis.

In order for the case to be categorized as no groin problems, players have to report full participation, no reduction in volume, no effect on performance, AND no pain related to football participation. In order for the case to be categorized as a groin problem, the player must report any form of reduction in participation, volume, performance OR any pain. In order for the case to be categorised as a substantial groin problem the player must report that the problems cause inability to participate in training and matches OR moderate or major reductions when responding to question 2 and 3. The responses to each of the four questions are allocated a numerical value from 0 to 25, and these are summed in order to calculate a severity score from 0 to 100.

Adductor Strengthening Program (ASP)
Level Exercise
3 Copenhagen Adduction
2 Copenhagen Adduction with shorter lever arm
1 Side lying hip adduction of lower leg

The ASP is a groin injury prevention program designed to increase hip adductor strength. Intervention groups teams are asked to implement the program during a 6-8 weeks period of the pre-season training and maintain it throughout the regular season with a lower frequency (table 2). The ASP consists of three levels, with one exercise at each level, where the players start on level 3. If a player experiences pain during the exercise >3 on a 0-10 on a numerical rating scale, where 0 is no pain and 10 is maximal pain, when performing the exercise on level 3, he will level down to ASP level 2, to reduce resistance and thus pain provocation. If ASP level 2 provokes pain >3 on a 0-10 on a numerical rating scale, the player will level down to ASP level 1 At all levels, the exercise is performed on both sides.

Copenhagen Adduction (level 3)
The CA is a partner exercise where the player lies on the side with one forearm as support on the floor and the other arm placed along the body. The superior leg is held in approximately the height of the hip of the partner, who holds the leg with one arm supporting the ankle and the other supporting the knee. The player then raises the body from the floor and the inferior leg is adducted so that the feet touch each other and the body is in a straight line. The body is then lowered halfway to the ground while the foot of the inferior leg is lowered so that it just touches the floor without using it for support. The tempo is as slow as possible without stopping the movement on the way.

Copenhagen Adduction with shorter lever arm (level 2)
At level 2 the CA exercise is performed as described in level 3, however with a shorter lever arm and both arms supporting the knee and lower thigh. The tempo is as slow as possible without stopping the movement during the exercise.

Side lying hip adduction (level 1)
The player lies on the side of the inferior leg with the dominant leg straight and the superior leg flexed 90° at the hip and knee. Maximal hip adduction of the dominant leg is performed keeping the knee straight and foot horizontal. The tempo is as slow as possible without stopping the movement during the exercise.

Protocol for the ASP
Weekly sessions Set/Side Repetitions/Side
Week 1 2 1 3-5
Week 2 3 1 3-5
Week 3-4 3 1 7-10
Week 5-6 3 1 12-15
Week 7-8 2 1 12-15
Week 9+ 1 1 12-15

Follow-up of injured players
Players reporting a groin injury to Idrettens Helsesenter (IHS), eligible to insurance coverage, will be invited to a standardized physical examination by a specialist in groin injuries. The groin injury specialists are eight experienced physiotherapists, working with football players, recruited by OSTRC and trained in the examination protocol by physiotherapist Kristian Thorborg prior to the project start. The groin injuries will be classified according to the clinical entities according to the Doha agreement, and players will be asked to complete the HAGOS4 questionnaire. If the physiotherapist is unsure on the clinical entity, a differential diagnosis not to be missed, or the groin injury becomes a long-standing problem (>6 weeks), the player will be invited to a clinical examination at IHS by Consultant in Sports Medicine Thor Einar Andersen.

Additional data registered
At baseline, we will register demographic data and HAGOS4 for players in both groups. On a weekly basis, players will self-report time loss due to illness or injuries to other body parts, as well as training and match exposure, through the smartphone application (Spartanova, Ghent, Belgium). Players in the intervention group will also report weekly compliance with the ASP.

Data management
A data handler employed at OSTRC will extract the weekly registrations from the Spartanova database. The data handler will be blinded to players' group assignment. He will sort data, and make them ready for statistical analyses. Data will be stored in a database at OSTRC and locked from revision by the principal investigator.

Missing data
For the intention to treat analyses all players will be included in the analyses. If the response rate is sufficient, we will estimate missing values using multiple imputation (MI). Multiple imputation will be based on the Multivariate Imputation by Chained Equation algorithm in combination with a predictive mean matching approach, which leads to the pooled results of five multiple imputed datasets. If the response rate is insufficient to perform MI, we will use last observation carried forward to impute missing data.

For the per-protocol analyses, we will exclude players without any football exposure due to illness or injury to another body part than the groin from the analyses for the period in question. However, players without any exposure to football due to a groin injury will be included in the analyses for the period in question. From the per-protocol analyses, we will also exclude players reporting less than 50% of the weekly registrations, or have a compliance less than 2/3 of the total training sessions with the ASP during pre-season (from inclusion in February to start of the regular season 9th April) or less than 50% of the training sessions with the ASP during the regular football season (from 9th April to 22nd October).

Statistics
We will perform intention-to-treat and per-protocol analyses for both primary and secondary outcome measures.

The prevalence of groin problems will be calculated in both groups by dividing the number of players who report any problem (i.e. anything but the minimum value in any of the four questions) by the number of questionnaire respondents. The average prevalence of groin problems will be calculated by summing up weekly prevalence measures and dividing them by the number of measures completed.

The prevalence of substantial groin problems will be calculated by dividing the number of players who report substantial groin problems by the number of questionnaire respondents.. The average prevalence substantial groin problems will be calculated by summing up the weekly prevalence measures and dividing them by the number of measures completed.

In order to assess differences in the prevalence (both any groin problems and substantial groin problems) between the intervention and control group over time, generalized estimating equations (GEE) will be performed. An exchangeable covariance matrix will be used and the significance level (α) will be 0.05 for all analyses. Any anthropometric or demographic variables showing a possible difference between groups at baseline ($p<0.2$) will be added to the GEE models using a forward selection procedure. Variables will be kept in the model if adding them causes a change in the beta-coefficient of at least 10%. All analyses will be performed using SPSS statistical software (SPSS V.21, IBM Corporation, New York, USA).

The severity score ranges from 0 to 100 and will be calculated on the basis of the four questions in the OSTRC Overuse Injury Questionnaire for every player reporting a groin problem and substantial groin problem in both groups. This will be done by allocating all response options with a numerical value from 0 to 25, and summing the responses to each of the four questions to give a score from 0 to 100. Questions 1 and 4 are scored 0-8-17-25 and questions 2 and 3 are scored 0-6-13-19-25. The severity score for all the players will be summed up and divided by the number of respondents for each measure. The average severity score for groin problems and substantial groin problems reported will be calculated by summing up the weekly measures of the severity score and dividing them by the number of measures completed.

Intervention Type
Other

Primary outcome(s)
Prevalence of all groin problems registered during the competitive season from mid-April, after at least 6 weeks of performing the ASP. The first registration included in the analyses will be on Sunday 10th April and the last registration will be on Sunday 23rd October. Registrations during the two-week summer break (from 26th June to 16th July or from 10th to 30th July) will not be included in the analyses.

Key secondary outcome(s))
1. Prevalence of substantial groin problems registered during the competitive season
2. The severity score of all groin problems and substantial groin problems registered during the competitive season

Completion date
01/11/2016

Eligibility

Key inclusion criteria
Male football players playing on the second or third level of senior Norwegian football

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Sex
Male

Total final enrolment
652

Key exclusion criteria
1. Foreign players who because of linguistic reasons are unable to answer the OSTRC Overuse Injury Questionnaire in Norwegian or English
2. Players who at the start of the project in February are injured or have an illness and not expected to return to training or match play during the first 6 to 8 weeks of the project

Date of first enrolment
08/02/2016

Date of final enrolment
01/03/2016

Locations

Countries of recruitment
Norway

Study participating centre
Oslo Sports Trauma Research Center (Norway)
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Sponsor information

Organisation
Oslo Sports Trauma Research Center

ROR
https://ror.org/018ct3570

Funder(s)

Funder type
Not defined

Funder Name
Oslo Sports Trauma Research Center

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019	17/05/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes