A neuromuscular warm-up program to prevent injuries in basketball – a cluster-randomized controlled trial

Study Type:	A cluster-randomized controlled trial
Risk Categorisation:	Risk category A according to HRA (low risk)
Study Registration:	The study will be registered at the «Koordinationsstelle Forschung am Menschen» (kofam: https://www.kofam.ch/). The trail has been registered at the «ISRCTN registry» (https://www.isrctn.com/).
Sponsor:	Oliver Faude, Department of Sport, Exercise and Health, University of Basel, Birsstr. 320B, 4052 Basel, oliver.faude@unibas.ch
Principal Investigator	Emilija Stojanović, Department of Sport, Exercise and Health, University of Basel, Birsstr. 320B, 4052 Basel, stojanovic.emilija@yahoo.com
Investigated Intervention:	A specifically designed five-phase (20 min) neuromuscular warm-up protocol will be integrated within the regular training routines. At the beginning of the season, each coach will obtain an exercise manual including a detailed description of the setup, all the exercises (including different difficulty levels), and additional background information concerning posture corrections and proprioception Intervention components are designed to include running (running straight ahead, running high-knees, running glute-kick, hip out, hip in, leg crossovers), plyometrics, balance, strength (walking lunge, double leg jump – double leg landing, single leg jump to double leg jump, double leg jump – highest point catch – double leg landing, single leg jump – highest point catch – single leg landing, double leg jump – two handed pass, wall sit, ball release core rotations, plank, side plank) and agility drills (mirror forwards and backwards, mirror side shuffle), replicating a basketball-specific workload as recommended from the literature. Teams from the control group will be instructed to perform their usual warm-up routine.

PROTOCOL SIGNATURE FORM

Study Title	A neuromuscular warm-up program to prevent injuries in basketball – a cluster-randomized controlled trial

The Sponsor has approved the protocol version 1 (dated 22/07/2021) and confirm hereby to conduct the study according to the protocol, current version of the World Medical Association Declaration of Helsinki, and ICH-GCP guidelines as well as the local legally applicable requirements.

Sponsor:

Name: *Oliver Faude*

Date: 13.09.2021 _____ Signature: _____

Principal Investigator:

Name: *Emilija Stojanović*

Date: 13.09.2021 _____ Signature: _____

TABLE OF CONTENTS

GLOSSARY OF ABBREVATIONS

AE	*Adverse Event*
ASR/DSUR	*Annual Safety Repot / Development Safety Report*
BASEC	*Business Administration System for Ethical Committees*
CRF	*Case Report Form*
CTCAE	*Common Terminology Criteria for Adverse Events*
FADP	*Federal Act on Data Protection (in German: DSG, in French: LPD, in Italian: LPD)*
eCRF	*electronic Case Report Form*
FOPH	*Federal Office of Public Health*
GCP	*Good Clinical Practice*
HRA	*Human Research Act (in German: HFG, in French: LRH, in Italian: LRUm)*
ICH	*International Conference on Harmonisation*
ClinO	*Ordinance on Clinical Trials in Human Research (in German: KlinV, in French: OClin, in Italian: OSRUm)*
SAE	*Serious Adverse Event*

1 STUDY SYNOPSIS

Sponsor / Principal Investigator	PD Dr. Oliver Faude
Title of Study	A neuromuscular warm-up program to prevent injuries in basketball – a cluster-randomized controlled trial
Short title	A neuromuscular warm-up program to prevent injuries in basketball
Version and date of protocol	02 (28.09.2022)
Study Registration	The study will be registered at the «Koordinationsstelle Forschung am Menschen» (kofam: https://www.kofam.ch/). The trial has been registered at the «ISRCTN registry» (https://www.isrctn.com/).
Study Category	A
Background	Basketball players have an increased risk of lower body injuries (especially knee and ankle). These injuries typically occur during single-leg jump landings. Because severe injuries carry the risk of long-term health consequences and prolonged interruptions in athletic activities and/or an active lifestyle, preventive measures are essential.
Risk-benefit assessment	Intervention-related foreseeable risks and/or discomforts (physical) that could reasonably be anticipated are lower than those encountered in regular training and competition. Participants from the intervention group will be instructed to focus on proper technique, movement awareness, and body positioning during warm-up, thereby minimizing the injury risk. Due to data safety reasons and to comply with the data privacy protection, all data will be stored separately from any names or other direct identification of participants. In addition, the records will be stored electronically on password-protected computers in Excel files at all times. Only research personnel will have access to participant personal data.
Study aim	The aim of this study is to assess the effectiveness of a specifically designed five-phase neuromuscular warm-up protocol (which incorporates basketball-specific drills) in reducing the incidence rate of injuries.
Endpoints	Primary endpoint: Incidence rate of lower extremity injuries Secondary endpoints: Incidence rate of … … overall injuries … severe injuries (lay-off time of more than 28 days) … joint-ligament injuries … muscle injuries … ankle injuries … knee injuries … upper extremity injuries
Study design	A two-arm, single-centre cluster-randomised controlled trial (level of evidence 1)
Statistical considerations	R (Project for Statistical Computing) and Jamovi will be used for statististical analyses. The injury incidence rate will be calculated as follows: [(number of events during a specified period)/(total athlete-exposures at risk during a specified period)] x 1000. We will calculate incidence rate ratios together with 95% confidence intervals to assess the risk difference between the intervention and the control group.
Inclusion and exclusion criteria	Inclusion criteria 1) ≥16 years of age; 2) >2 years' experience in organized basketball training and competition immediately prior to participation in the study; 3) officially registered teams. Exclusion criteria 1) regular training takes place less than twice per week; 2) teams already apply an injury prevention program or a structured warm-up focusing on neuromuscular control. No restrictions will be set according to sex.
Sample size	An a priori analysis using G*Power software (version 3.1.7; Heinrich Heine University Düsseldorf, Düsseldorf, Germany) for proportions (using a 2-tailed alpha value of 0.05, and power of 0.80) recommended a sample size of 124 (62 per group), based on previous research

	reporting a total of 32 injuries (17.5% in intervention group compared to 41.4% in control group) during the 9-month season.
Intervention	A specifically designed five-phase (20 min) neuromuscular warm-up protocol will be integrated within the regular training routines. At the beginning of the season, each coach will obtain an exercise manual including a detailed description of the setup, all the exercises (including different difficulty levels), and additional background information concerning posture corrections and proprioception. Intervention components are designed to include running (running straight ahead, running high-knees, running glute-kick, hip out, hip in, leg crossovers), plyometrics, balance, strength (walking lunge, double leg jump – double leg landing, single leg jump to double leg jump, double leg jump – highest point catch – double leg landing, single leg jump – highest point catch – single leg landing, double leg jump – two handed pass, wall sit, ball release core rotations, plank, side plank) and agility drills (mirror forwards and backwards, mirror side shuffle), replicating a basketball-specific workload as recommended from the literature.
Control	Teams from the control group will be instructed to perform their usual warm-up routine.
Study conduct	Eligible participants will be randomly assigned to a control or intervention group. A specially designed five-phase (20-minute) neuromuscular warm-up protocol will be incorporated into regular training routines in the intervention group. Teams in the control group will be instructed to perform their usual warm-up program. During the first weeks of the season, study assistants will visit the intervention group teams and provide instruction to the coaches on the proper use of the intervention program. In addition, two unannounced visits (by study assistants) will be made to each team in the intervention group during the study period. For each team, the contact person (preferably, but not necessarily, the coach) will be instructed to report injuries that occurred during a scheduled game or practice session that resulted in the player being unable to complete the current game or practice session and/or fully participate in the next game or practice session. The characteristics of the injury, including location, type, and mechanism, as well as the time the player was unable to participate in the sport, will be reported by the coach or other contact person (therapist, physician) on a weekly injury report form via email to the researcher (who is blind to group assignment). If an athlete is injured we will contact her/him to find out the more specific circumstances of the injury. If an injury requires medical treatment, we will ask the athlete to get the exact diagnosis from the treating physician.
Study duration and time plan	The study begins in September 2021 and will end in June 2022. In September athletes and coaches will be instructed on the coduct of the training programme and on the proper reporting of exposure times and injuries. Data acquisition starts mid-September. First-Participant-In: 15.09.2021 Last-Participant-Out: 30.06.2022
Research team	**PD Dr. Oliver Faude** Head Section Exercise and Movement Science Department of Sport, Exercise and Health, Medical Faculty, University of Basel Address: Birsstrasse 320B, CH-4052 Basel T +41 61 207 4735 Email: oliver.faude@unibas.ch **Dr. Emilija Stojanović** Department of Sport, Exercise and Health, Medical Faculty, University of Basel Address: Birsstrasse 320B, CH-4052 Basel stojanovic.emilija@yahoo.com
Study center	Department of Sport, Exercise and Health, Medical Faculty, University of Basel
Data security	The principal investigator/sponsor confirms and defends the principle of the right to privacy of the participants. This means that both the applicable data protection laws will be complied with and the anonymity of the participants will be guaranteed when the data are presented at scientific meetings or published in scientific journals. Medical information about individual subjects obtained in the course of this study is considered confidential. In this regard, disclosure to third parties is prohibited. Confidentiality is further assured by the use of subject identification numbers corresponding to treatment data in computer files. Participant data will be handled with uttermost discretion and will be only accessible to authorised personnel who require the data to fulfil their duties within the scope of the study.

	On the CRFs and other study specific documents, participants will be only identified by a unique participant number. The principal investigator will retain a confidential master list linking the participants' unique study numbers with participant names. The records will be stored electronically on password-protected computers in Dropbox folder to ensure safety back-ups or protect from unauthorised or accidental disclosure, alteration, deletion, copying and theft. In addition, all files will be secured in locked cabinets.
Ethical considerations	The high participation in sports activities has resulted in sports being the primary cause of injury, with probably the highest injury rates in competitive athletes. Many injuries most often leads to decline in performance, loss of playing time, a high financial burden for the athlete's employer as well as the healthcare system, and an increased risk of re-injury and chronicity. In this regard, prevention of basketball injuries would be beneficial to basketball players, teams, the Swiss Basketball Federation, health insurance companies, and society. To date, the equivocal findings have been reported regarding the effect of neuromuscular training on the incidence rate of injury in basketball players. Although neuromuscular training has the potential to enhance stability, muscular strength, motor control and reduce the risk of injury, injury prevention program should be designed to better replicate basketball-specific movement patterns. The risk of injury will be minimized by using research participants that have experience with neuromuscular training, placing the focus on proper technique, movement awareness, body positioning and basketball-specific activity demands. All data will be handled with uttermost discretion and will be only accessible to participant or authorised personnel who require the data to fulfil their duties within the scope of the study. Participant may choose not to participate or you may discontinue your participation at any time without penalty.
GCP declaration	This study will be conducted in accordance with the current version of the Declaration of Helsinki, the ICH-GCP, the HRA as well as relevant local legal and regulatory requirements.

2 BACKGROUND AND RATIONALE

Basketball is a sport that places high demands on the lower extremities, which can lead to an increased risk of injury. The lower limbs (63.7%) are the most affected injury region in basketball players (1). Two basketball-related injuries that traditionally receive the most attention are ankle sprains and knee injury [particularly of the anterior cruciate ligament (ACL)], accounting for 15% and 23% of all basketball injuries in males and females (2). Sports-related injuries are a substantial contributor to the health care costs in Switzerland, estimated at over 931 million Swiss francs per year, of which the highest costs resulted from ACL reconstruction, particularly in team sports (3). Epidemiological data reveal a worrying increase in the incidence of ACL reconstructions in young athletes (4). An ACL injury has serious consequences for the injured athlete, in terms of not only treatment costs and time lost from sport, but also a greatly increased risk of early osteoarthritis. While ankle sprains are relatively less severe than ACL injury in terms of time lost from sport, prevention efforts are important, considering the increased risk of recurrent sprain, concomitant injury to the talus and peroneal musculature, and the development of chronic ankle instability (5, 6) with subsequent osteoarthritis that can follow initial ankle sprains (7).

Given the high incidence rates and long-term consequences associated with ankle and ACL injury, extensive research (8-17) has been performed to design and implement injury prevention programs in basketball players; however, with equivocal findings. To date, eight studies (10-17) have examined the effects of injury prevention programs on the incidence rate of lower extremity injuries [six studies for ankle injury (10-14, 16) and knee injury (10-12, 15-17)] in basketball players. While some prevention programs have been found to be effective in reducing lower extremity injuries [ankle(10, 13) and knee(12)], the majority of the existing studies show non-significant differences on decreasing the risk of ankle injury (4 out of 6 studies = 67%)(11, 12, 14, 16) and knee injury (5 out of 6 studies = 83%) (10, 11, 15-17). In addition, two meta-analyses by Taylor et al. (6) and Michaelidis et al. (18) failed to show any effect of prevention programs on ACL knee injury rate in basketball players. While Taylor et al. (6) confirmed the effectiveness of neuromuscular training and external support (e.g. ankle bracing) on reducing the risk of ankle sprains, the precise influence of the training procedure remains unclear since a pooled meta-analytic approach was applied.

Despite growing interest in quantifying the effects of injury prevention programs in basketball players, there are still many practical aspects that should be addressed. To date, injury prevention programs have been uniformly implemented across basketball and soccer athletes. Since "FIFA 11+" has been shown to be effective in preventing injuries in soccer players (19), two studies (11, 16) have implemented this program in male and female basketball players, showing no reduction in ankle and knee injury rates. The implementation of an injury prevention program, which was developed for a specific sport like soccer, with a majority of the plyometric exercises emphasizing double-leg sagittal plane movements, may not be appropriate for basketball players, considering differences in activity demands between basketball and soccer (20). While both sports are multi-directional, basketball requires more abrupt stops, cutting, movements in the frontal plane (e.g. lateral shuffling), and single-leg jump landings than soccer on a different surface (21, 22). These basketball-specific tasks impose elements of dynamic lower extremity valgus, placing basketball players in potentially higher-risk positions for ACL injuries, which typically occur during single-leg jump landings (about 70%) (20). Therefore, an injury prevention program should be developed to better replicate the multidirectional, high-intensity activity demands experienced during game-play. Focus on basketball-specific movement patterns and the correct technique might contribute to the development of more adequate interventions and to the selection of effective strategies in reducing and minimizing the risk of injury in basketball players. Considering the role of the feedback in effective teaching motor skill and neuromuscular control, foreseeable risks and/or discomforts (physical) that could reasonably be anticipated during specifically designed warm-up are lower than those encountered in regular training and competition (A category according to ClinO, Art. 61).

3 STUDY OBJECTIVES AND DESIGN

3.1 Hypothesis and primary objective

Hypothesis:
A specifically designed training program can be effective in reducing the incidence rate of injury in basketball players.
Objective:
The aim of this study is to assess the effectiveness of a specifically designed five-phase neuromuscular warm-up protocol (which incorporates basketball-specific drills) in reducing the incidence rate of injuries.

3.2 Primary and secondary endpoints

Primary endpoint:
Incidence rate of lower extremity injuries

Secondary endpoints:
Incidence rate of …
… overall injuries
… severe injuries (lay-off time of more than 28 days)
… joint-ligament injuries
… muscle injuries
… ankle injuries
… knee injuries
… upper extremity injuries

3.3 Study design

A two-arm, cluster-randomised controlled trial (level of evidence 1) will be adopted in this study, and conducted as a single-centre study in Switzerland. To reduce potential confounding, the teams will be matched by sex and playing level. All teams will be randomly allocated to a control

or intervention group in a 1:1 ratio. The researcher who conduct the randomization will not be involved in the intervention, and recruitment will be completed before randomization. Computer-generated cluster randomization will be conducted using Research Randomizer software (https://www.randomizer.org/).

3.4 Study intervention

A specifically designed five-phase (20 min) neuromuscular warm-up protocol will be integrated within the regular training routines. At the beginning of the season, each coach will obtain an exercise manual including a detailed description of the setup, all the exercises (including different difficulty levels), and additional background information concerning posture corrections and proprioception. Intervention components are designed to include **running** (running straight ahead, running high-knees, running glute-kick, hip out, hip in, leg crossovers), **plyometrics, balance, strength** (walking lunge, double leg jump – double leg landing, single leg jump to double leg jump, double leg jump – highest point catch – double leg landing, single leg jump – highest point catch – single leg landing, double leg jump – two handed pass, wall sit, ball release core rotations, plank, side plank) and **agility drills** (mirror forwards and backwards, mirror side shuffle), replicating a basketball-specific workload as recommended from the literature. Teams from the control group will be instructed to perform their usual warm-up routine, including light aerobic exercises, basketball and team drills, and dynamic stretching.

Upon regular study completion, participants from both groups (intervention and control) may choose their preferable warm-up routine (specifically designed or usual).

4 STUDY POPULATION AND STUDY PROCEDURES

4.1 Inclusion and exclusion criteria, justification of study population

Officially registered basketball teams in Switzerland will be invited to participate in the study. The following inclusion criteria will be applied: 1) ≥16 years of age; 2) >2 years' experience in organized basketball training and competition immediately prior to participation in the study; 3) officially registered teams. Teams will be excluded if 4) regular training takes place less than twice per week; 5) teams already apply an injury prevention program or a structured warm-up focusing on neuromuscular control (apart from light aerobic exercise, basketball and teams drills, and dynamic stretching). No restrictions will be set according to sex. Initial screening questions will qualify or disqualify respondents from taking the study.

4.2 Recruitment, screening and informed consent procedure

Officially registered basketball teams competing in the first, second and third division of the Swiss Basketball League will be invited (via e-mail) to participate in this study in August till mid-September 2021. Information meetings will be also conducted to inform coaches about the aims and procedures of the study and, for intervention group only, to give detailed instructions and practical application on the warm-up programme. The institutional/organizational permission will be obtained to ensure access to all members of the basketball team before recruiting participants. Potential participants maintain their right to refuse or withdraw from participation. To protect the privacy interests and minimize the possibility of undue influence (e.g. peers), decision to take part in the research will be made in the absence of other team members."

The investigators will explain to each participant the nature of the study, its purpose, the procedures involved, the expected duration, the potential risks and benefits and any discomfort it may entail. Each participant will be informed that the participation in the study is voluntary and that he or she may withdraw from the study at any time and that withdrawal of consent will not affect his or her subsequent medical assistance and treatment. The participant will be informed

that his or her medical records may be examined by authorised individuals other than their treating physician. Two weeks will be given to the potential participant to consider fully the likely implications of the research before making a decision.

The formal consent from all participants with parental consent for those <18 years of age (using the approved consent form) will be obtained before the participant is submitted to any study procedure. The consent form will be signed and dated by the investigator or his designee at the same time as the participant sign. A copy of the signed informed consent will be given to the study participant. The consent form will be retained as part of the study records. No compensation will be provided to the study participants.

4.3 Study procedures

The observation period will comprise one basketball season from September/October 2021 to May/June 2022. To ensure recruitment of participants, an information sheet containing exclusion/inclusion criteria will be distributed to all basketball teams in August 2021. After signing informed consent forms, eligible participants will be assigned to a control or intervention group in a 1:1 ratio. Teams who meet an acceptance rate of 70% from the roster list will be included in the study.

Data on medical history, age, height, body mass, training characteristics, injury history, basketball experience, and competition level will be collected at baseline. Injury characteristics, including location, type, mechanism, as well as time loss from sport will be reported by the coach or other contact person (therapist, medical doctor) on a weekly injury report form to the researcher (blinded to group allocation) via email (23). For each team, the contact person (preferably, but not necessarily the coach) will be instructed to report injuries that occurred during a scheduled match or training session, causing the player to be unable to complete the current match or training session and/or to fully take part in the next match or training session. If an injury requires medical treatment, basketball player will be instructed to obtain the exact diagnosis from the treating physician. Injury rates will be reported as number of injuries per 1000 athlete exposures. Exposure is defined as one athlete participating in one practice or match. Coaches will register individual playing time (min) and absences (due to an injury) for each training session and match during the season.

4.4 Withdrawal and discontinuation

Participants may be withdrawn from the study due to a safety concern or if judged non-compliant with trial procedures. The participant must be withdrawn from treatment if one of the following applies:

- Participant decide to stop taking part in this study at any time
- Pregnancy during study duration
- Major violation of the study protocol

In case of withdrawal, identifiable data of participants will be kept confidential. All data will be stored separately from any names or other direct identification of participants.

5 STATISTICS

5.1 Statistical analysis plan and sample size calculation

An a priori analysis using G*Power software (version 3.1.7; Heinrich Heine University Düsseldorf, Düsseldorf, Germany) for proportions (using a 2-tailed alpha value of 0.05, and power of 0.80) recommended a sample size of 124 (62 per group), based on previous research (7) reporting a total of 32 injuries (17.5% in intervention group compared to 41.4% in control group) during the 9-month season. The injury incidence rate will be calculated as follows: [(number of events during a specified period)/(total athlete-exposures at risk during a specified period)] x 1000. We will calculate incidence rate ratios together with 95% confidence intervals to assess the risk difference

between the intervention and the control group. The exposure time will be calculated as (1) participation hours and (2) athlete-exposure. The participation hours will be calculated for each group as the sum of the number of exposure hours of each player (match exposure time, training exposure time, total exposure time = match + training hours). The athlete-exposure will be calculated for each group as the number of athletes participating in each game or training session (for example, a team of 10 athletes who participated in 5 games and 50 team practices would accumulate 50 athlete games and 500 athlete practices for a total of 550 athlete-exposures). Differences in participation hours and athlete-exposure between the intervention and control groups will be assessed using the independent t test (if data follows normal distribution) or Mann-Whitney U test (if data does not follow normal distribution). Data analyses will be performed using R. Any deviation from the original statistical plan will be described and justified in the final trial report.

5.2 Handling of missing data and drop-outs

All randomized subjects will be included in the group which they were originally assigned, regardless of adherence to treatment protocol (eg, dropout/withdrawal or protocol deviations). Thus, all data will be analyzed on an intention-to-treat basis. The missing data will replaced with the last observation carried forward.

6 REGULATORY ASPECTS AND SAFETY

6.1 Local regulations / Declaration of Helsinki

The study protocol will be approved by the regional ethics committee (Ethikkommission Nordwest- und Zentralschweiz) and conducted in compliance with the Declaration of Helsinki.

6.2 (Serious) Adverse Events

Considering the role of the feedback in effective teaching motor skill and neuromuscular control, intervention-related foreseeable risks and/or discomforts (physical) that could reasonably be anticipated are lower than those encountered in regular training and competition (A category according to ClinO, Art. 61). Participant may experience one or more of the risks indicated below from participating in this study:

- There is a risk for injury (related to the trial intervention: possibly; severity: mild) if proper form and technique are not utilized. The risks will be minimized by focusing on proper technique, movement awareness, body positioning and basketball-specific activity demands, along using trained technicians (e.g. strength and conditioning coaches) as well as research participants that have experience with neuromuscular training.
- After exercise, muscle soreness (related to the trial intervention: possibly; severity: mild) may be present for the next 24-48 hours.

There may be other unknown risks, or risks that we do not anticipate, associated with participation in this study.

Reporting of SAEs (see ClinO, Art. 63)

An AE that meets the criteria for a SAE will be documented and reported immediately (within a maximum of 24 hours) to the investigator of the study as an SAE. If it cannot be excluded that the SAE occurring in Switzerland is attributable to the intervention under investigation, the Investigator will report it to the Ethics Committee via BASEC within 15 days. Since only healthly participants will be recruited, SAEs will not be exempted from expedited reporting.

Follow up of (Serious) Adverse Events

All SAEs will be followed until resolution, or until the condition has stabilized with no further change.

6.3 (Periodic) safety reporting

After study termination, an annual safety report (ASR/DSUR) will be submitted to the local Ethics Committee by the Investigator (ClinO, Art. 43 Abs).

6.4 Radiation

To minimize radiation exposure to the participant, imaging procedure or other exams will be performed only when necessary (e.g. injury) to answer a medical question or treat a disease. If the permitted dose guidance value (5 mSv per year if no direct benefit is expected for the participants) is exceeded at any time, the local Investigator will notify the Ethics Committee via BASEC within 7 working days of it becoming known (see ClinO, Art. 44).

6.5 Pregnancy

Pregnant women will not be allowed to participate in this study. If become pregnant during the study, participant must report it immediately (within a maximum of 24 hours) to the Investigator, and will be withdrawn from the study.

6.6 Amendments

The protocol and relevant study documents are submitted to the Ethics Committee for approval before implementation. Under emergency circumstances, deviations from the protocol to protect the rights, safety and well-being of human subjects may proceed without prior approval of the Ethics Committee. Such deviations shall be documented and reported to the Ethics Committee as soon as possible.

Substantial amendments are changes that affect the safety, health, rights and obligations of participants, changes in the protocol that affect study objective(s) or central research topic, changes of study site(s) or of study leader and sponsor (ClinO, Art. 29).

A list of substantial changes is also available on www.swissethics.ch.

A list of all non-substantial amendements will be submitted once a year to the competent EC together with the ASR.

6.7 (Premature) termination of study

The Sponsor-Investigator may terminate the study prematurely according to certain circumstances, e.g.

- Ethical concerns,
- When the safety of the participants is doubtful or at risk (e.g. when the benefit-risk assessment is no longer positive),
- Alterations in accepted clinical practice that make the continuation of the study unwise, or
- Early evidence of harm of the experimental intervention

Upon regular study termination, the Ethics Committee will be notified via BASEC within 90 days (ClinO, Art. 38).

Upon premature study termination or study interruption, the Ethics Committee will be notified via BASEC within 15 days (ClinO, Art. 38).

Due to data safety reasons and to comply with the data privacy protection, all data will be stored separately from any names or other direct identification of participants. In addition, the records will be stored electronically on password-protected computers in Excel files at all times. All names

or other direct identification of participants will be destroyed upon completion of project life, while data regarding injury occurrence will be maintained in storage for a period of 10 years after completion of the study.

6.8 Insurance

Study-related damages are covered by the liability insurance of the Department of Sport, Exercise and Health of the University of Basel except in the case of a claim due to misconduct.

7 FURTHER ASPECTS

7.1 Overall ethical considerations

The high participation in sports activities has resulted in sports being the primary cause of injury, with probably the highest injury rates in competitive athletes. Many injuries most often leads to decline in performance, loss of playing time, a high financial burden for the athlete's employer as well as the healthcare system, and an increased risk of re-injury and chronicity. In this regard, prevention of basketball injuries would be beneficial to basketball players, teams, the Swiss Basketball Federation, health insurance companies, and society. To date, the equivocal findings have been reported regarding the effect of neuromuscular training on the incidence rate of injury in basketball players. Although neuromuscular training has the potential to enhance stability, muscular strength, motor control and reduce the risk of injury, injury prevention program should be designed to better replicate basketball-specific movement patterns. The risk of injury will be minimized by using research participants that have experience with neuromuscular training, placing the focus on proper technique, movement awareness, body positioning and basketball-specific activity demands. All data will be handled with uttermost discretion and will be only accessible to participant or authorised personnel who require the data to fulfil their duties within the scope of the study. Participant may choose not to participate or you may discontinue their participation at any time without penalty.

7.2 Risk-benefit assessment

Intervention-related foreseeable risks and/or discomforts (physical) that could reasonably be anticipated are lower than those encountered in regular training and competition. Participants from the intervention group will be instructed to focus on proper technique, movement awareness, and body positioning during warm-up, thereby minimizing the injury risk.

Due to data safety reasons and to comply with the data privacy protection, all data will be stored separately from any names or other direct identification of participants. In addition, the records will be stored electronically on password-protected computers in Excel files at all times. Only research personnel will have access to participant personal data.

8 QUALITY CONTROL AND DATA PROTECTION

8.1 Quality measures

Data entry will be performed by a single investigator (single data entry) and checked for accuracy and completeness by another investigator. The principal investigator is qualified and have sufficient resources and appropriately trained staff to conduct the investigation and is knowledgeable of the national setting and circumstances of the site and study population. The principal investigator will be in regular contact with the coaches, i.e. by phone/mail and by site visits on the pitch. In addition, study assistants will visit the teams in the intervention group and give the coaches an instruction session on how to apply the intervention programme correctly.

For quality assurance the sponsor, the Ethics Committee or an independent trial monitor may visit the research sites. Direct access to the source data and all study related files will be

granted on such occasions. All involved research personnel will keep the participant data strictly confidential.

8.2 Data recording and source data

Case Report Form (CRF) will be designed in consonance with the Protocol (as a source document), to record data and other information on each trial subject. CRF pages will be identified only by the participant's unique study number to maintain the participant's confidentiality. The principal investigator will retain a confidential master list linking the participants' unique study numbers with participant names; this will be accessible only those working on study data retrieval.

The coaches of each team will be contacted by telephone and/or e-mail once a week to record all training and match activity, in addition to new injuries. Injured players will be interviewed by the injury recorders to assess aspects of the injury based on a standardized injury questionnaire. The injury recorders will be blinded to which group the teams and injured players belong to. If available, the physician's notes (e.g. diagnosis, treatment), imaging reports (e.g. magnetic resonance imaging, computed tomography, musculoskeletal ultrasound), and/or operative notes (e.g. left knee partial medial meniscectomy, left knee arthroscopic anterior cruciate ligament reconstruction with hamstring autograft) will be obtained to confirm diagnoses.

8.3 Confidentiality and coding

Participant data will be handled with uttermost discretion and will be only accessible to authorised personnel who require the data to fulfil their duties within the scope of the study. On the CRFs and other study specific documents, participants will be only identified by a unique participant number. The principal investigator will retain a confidential master list linking the participants' unique study numbers with participant names. The records will be stored electronically on password-protected computers in Excel files and Dropbox folder to ensure safety back-ups or protect from unauthorised or accidental disclosure, alteration, deletion, copying and theft. In addition, all files will be secured in locked cabinets.

8.4 Retention and destruction of study data and biological material

All study data will be maintained electronically for a period of 10 years after study termination or premature termination of the study.

9 MONITORIMG AND REGISTRATION

Department of Sport, Exercise and Health, University of Basel (Medical Faculty) will be responsible for the monitoring and ensuring high quality and timely inputs, and for ensuring that the project maintains its strategic vision and that its activities result in the achievement of its intended outputs in a cost effective and timely manner, under direct supervision by Dr. Oliver Faude.

During the first weeks of the season, study assistants will visit the teams in the intervention group and give the coaches an instruction session on how to apply the intervention programme correctly. The principal investigator will be in regular contact with the coaches, i.e. by phone/mail and by site visits on the pitch. Two unannounced visits will be undertaken (by study assistants) in each team during the study period. Injury characteristics, including location, type, mechanism, as well as time loss from sport will be reported by the coach or other contact person (therapist, medical doctor) on a weekly injury report form to the researcher (blinded to group allocation) via email. In addition, data concerning athlete exposure will be also collected.

Research data (source data/documents) will be accessible to monitors, and answers will be provided for each question during monitoring. This study will be registered on the SNCTP (Swiss National Clinical Trial Portal). The trial has been registered at the ISRCTN registry (https://www.isrctn.com/).

10 FUNDING / PUBLICATION / DECLARATION OF INTEREST

This study will be supported by the Swiss Government Excellence Postdoc Scholarship awarded by Federal Commission for Scholarships for Foreign Students FCS (Emilija Stojanović). Prior to the publication of the article arising from this project, each author is expected to: 1) have made substantial contributions to the conception or design of the work, OR the acquisition, analysis, or interpretation of data, OR have drafted the work or substantially revised it; 2) has approved the submitted version; 3) AND agrees to be personally accountable for the author's own contributions and for ensuring that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and documented in the literature. There is no conflict of interest directly relevant to the content of this project.

Appendix 1: Schedule of assessments (if applicable)

Time (hour, day, week)	**>-40 day**	**-30 days**	**-7 days**	**~ +60 days**	**~ +150 days**
Visit	Information	Screening	1st visit	2nd visit	3rd visit
Oral and written patient information	+				
Written consent		+			
Inclusion-/ exclusion criteria		+			
Medical history		+			
Physical examination		+			
Participant characteristics		+			
Procedures		+	+	+	+
Intervention			+	+	+
Questionnaire		+			
Safety		+	+	+	+

REFERENCES

1. Andreoli CV, Chiaramonti BC, Biruel E, de Castro Pochini A, Ejnisman B, Cohen M. Epidemiology of sports injuries in basketball: integrative systematic review. *BMJ Open Sport & Exercise Medicine*. 2018;4(1).
2. Cumps E, Verhagen E, Meeusen R. Prospective epidemiological study of basketball injuries during one competitive season: ankle sprains and overuse knee injuries. *Journal of Sports Science & Medicine*. 2007;6(2):204.
3. Gebert A, Gerber M, Pühse U, Gassmann P, Stamm H, Lamprecht M. Costs resulting from nonprofessional soccer injuries in Switzerland: A detailed analysis. *Journal of Sport and Health Science*. 2020;9(3):240-247.

4. Zbrojkiewicz D, Vertullo C, Grayson JE. Increasing rates of anterior cruciate ligament reconstruction in young Australians, 2000–2015. *Medical Journal of Australia*. 2018;208(8):354-8.
5. Miklovic TM, Donovan L, Protzuk OA, Kang MS, Feger MA. Acute lateral ankle sprain to chronic ankle instability: a pathway of dysfunction. *The Physician and Sportsmedicine*. 2018;46(1):116-22.
6. Taylor JB, Ford KR, Nguyen A-D, Terry LN, Hegedus EJ. Prevention of lower extremity injuries in basketball: a systematic review and meta-analysis. *Sports Health*. 2015;7(5):392-8.
7. Delco ML, Kennedy JG, Bonassar LJ, Fortier LA. Post-traumatic osteoarthritis of the ankle: A distinct clinical entity requiring new research approaches. *Journal of Orthopaedic Research*. 2017;35(3):440-53.
8. McGuine TA, Keene JS. The effect of a balance training program on the risk of ankle sprains in high school athletes. *The American Journal of Sports Medicine*. 2006;34(7):1103-11.
9. LaBella CR, Huxford MR, Grissom J, Kim K-Y, Peng J, Christoffel KK. Effect of neuromuscular warm-up on injuries in female soccer and basketball athletes in urban public high schools: cluster randomized controlled trial. *Archives of Pediatrics & Adolescent Medicine*. 2011;165(11):1033-40.
10. Riva D, Bianchi R, Rocca F, Mamo C. Proprioceptive training and injury prevention in a professional men's basketball team: a six-year prospective study. *Journal of Strength and Conditioning Research*. 2016;30(2):461.
11. Bartz H. Examining the Impact of Adding Gluteal Strengthening Exercises to the FIFA 11+ Warm-Up Program on High School GIrls' Basketball Reported Injuries. (Master's thesis). University of Montana; 2018. Available from https://scholarworks. umt.edu/cgi/viewcontent.cgi?article=12181&context=etd
12. Bonato M, Benis R, La Torre A. Neuromuscular training reduces lower limb injuries in elite female basketball players. A cluster randomized controlled trial. *Scandinavian Journal of Medicine & Science in Sports*. 2018;28(4):1451-60.
13. Eils E, Schröter R, Schröder M, Gerss J, Rosenbaum D. Multistation proprioceptive exercise program prevents ankle injuries in basketball. *Medicine & Science in Sports & Exercise*. 2010;42(11):2098-105.
14. Emery CA, Rose MS, McAllister JR, Meeuwisse WH. A prevention strategy to reduce the incidence of injury in high school basketball: a cluster randomized controlled trial. *Clinical Journal of Sport Medicine*. 2007;17(1):17-24.
15. Hewett TE, Lindenfeld TN, Riccobene JV, Noyes FR. The effect of neuromuscular training on the incidence of knee injury in female athletes. *The American Journal of Sports Medicine*. 1999;27(6):699-706.
16. Longo UG, Loppini M, Berton A, Marinozzi A, Maffulli N, Denaro V. The FIFA 11+ program is effective in preventing injuries in elite male basketball players: a cluster randomized controlled trial. *The American Journal of Sports Medicine*. 2012;40(5):996-1005.
17. Pfeiffer RP, Shea KG, Roberts D, Grandstrand S, Bond L. Lack of effect of a knee ligament injury prevention program on the incidence of noncontact anterior cruciate ligament injury. *The Journal of Bone & Joint Surgery*. 2006;88(8):1769-74.
18. Michaelidis M, Koumantakis GA. Effects of knee injury primary prevention programs on anterior cruciate ligament injury rates in female athletes in different sports: a systematic review. *Physical Therapy in Sport*. 2014;15(3):200-10.
19. Silvers-Granelli HJ, Bizzini M, Arundale A, Mandelbaum BR, Snyder-Mackler L. Does the FIFA 11+ injury prevention program reduce the incidence of ACL injury in male soccer players? *Clinical Orthopaedics and Related Research*. 2017;475(10):2447-55.
20. Taylor JB. *Differential biomechanical effects of an ACL injury prevention program in women's basketball and soccer players*. The University of North Carolina at Greensboro; 2016. Available from https://libres.uncg.edu/ir/uncg/listing. aspx?id=19816

21. Stojanović E, Stojiljković N, Scanlan AT, Dalbo VJ, Berkelmans DM, Milanović Z. The activity demands and physiological responses encountered during basketball match-play: A systematic review. *Sports Medicine*. 2018;48(1):111-35.
22. Taylor JB, Wright AA, Dischiavi SL, Townsend MA, Marmon AR. Activity demands during multi-directional team sports: a systematic review. *Sports Medicine*. 2017;47(12):2533-51.
23. Injury IOC, Group IEC, Bahr R et al. International Olympic Committee consensus statement: methods for recording and reporting of epidemiological data on injury and illness in sports 2020 (including the STROBE extension for sports injury and illness surveillance (STROBE-SIIS)). *Orthopaedic Journal of Sports Medicine*. 2020;8(2):2325967120902908.