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The effect of low volume Nordic hamstring exercise on physical performance in amateur youth football players

Submission date 19/09/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/09/2022	**Overall study status** Completed	
Last Edited 12/08/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Nordic Hamstring Exercise (NHE) is an effective hamstring injury prevention program but has low compliance issues among amateur and elite football players. Studies showed that Low volume NHE results in similar structural changes in muscle and is suggested as an alternative program with less side effects of Delayed Onset Muscle Soreness (DOMS), a factor that influences compliance. Another approach to convince the coaches and players of the program is to provide evidence of the program's effect on physical performance. Promoting the performance-enhancing effects may motivate them to implement the program consistently. The primary aim of this study is to determine the effects of the 8-week low volume of the NHE program on physical performance, which includes eccentric hamstring strength, sprint, vertical jump, and Change of Direction (CoD) performance in amateur male academy football players. In addition, we aim to investigate muscle soreness as a potential side effect of intervention experienced by subjects using the Numerical Rating Scale (NRS) for hamstring pain.

Who can participate?
This study requires 40 healthy male amateur youth football players aged 14-17 years old.

What does the study involve?
This is a randomized controlled trial (RCT) with 2-group parallel design. The intervention is a supervised 8-week low-volume Nordic Hamstring Exercise/NHE protocol (NHE group), and the control will perform the regular football training (CON group). The primary endpoints are change of eccentric hamstring strength, 30-m sprint, vertical jump, and CoD performance from baseline that will be recorded at an 8-week follow-up.

What are the possible benefits and risks of participating?
Benefit: The Low Volume Nordic Hamstring Exercise Program has a potential effect on improving football performance, but that is not certain. By participating, subjects contribute to knowledge with which we can better football performance in the future.

Risk: The program is not considered risky because they are existing exercises that are already used in daily practice. Especially at the beginning of the program, some muscle pain/soreness is often reported.

Where is the study run from?
Faculty of Sports Science, Universitas Negeri Yogyakarta, Indonesia
Faculty of Sports Science, Universitas Negeri Surabaya, Indonesia
Department of Orthopedic Surgery and Sports Medicine, Amsterdam UMC, The Netherlands

When is the study starting and how long is it expected to run for?
June 2022 to June 2023

Who is funding the study?
Investigator initiated and funded
This trial is supported by the Indonesia Endowment Fund for Education, Ministry of Finance, Republic of Indonesia, for Ph.D. program scholarship.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

00052134042112620220813090

Study information

Scientific Title
Low Volume Nordic Hamstring Exercise Research

Acronym
LOVENDER

Study objectives
We hypothesize that eight weeks of the low volume Nordic Hamstring Exercise (NHE) provide sufficient time to allow the physiological adaptation and contribute positive effect on eccentric hamstring strength, sprint, vertical jump and Change of Direction (COD)

Our secondary hypothesis is subjects in the intervention group will experience a very low level of hamstring pain as a side effect of the program

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/08/2022, Ethics Commission Universitas Negeri Yogyakarta (Jl. Colombo No. 1. Caturtunggal, Kec. Depok, Kabupaten Sleman, Daerah Istimewa Yogyakarta, Indonesia; +62 274 586168; lppm@uny.ac.id), ref: No.B/46/UN.34.21/TU/2022

Study design
Randomized superiority controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Healthy male amateur youth football players

Interventions

Randomization
Subjects are stratified by the football team and individually randomized to the Intervention (NHE)- or control group with the 1:1 allocation ratio using an online software application (sealed envelope™).

Intervention
Subjects in the NHE group will perform low volume NHE program in addition to their regular football training, while the CON group will only perform their regular football training. It consists of 10 sessions in 8 weeks of follow-up (144 reps of total volume and 21 reps of average weekly volume).

Study Setting
The intervention will be conducted during the regular football training schedule. The data collection procedures will be performed in a similar condition on the same football field with the same trained staff/tester.

Data Collection
Subject characteristics, including age (year), height (m), weight (kg), and BMI (kg/m2), will be collected in both groups. The physical performance tests as the primary outcome will be conducted twice, before and after the eight weeks of intervention.

Intervention Type
Behavioural

Primary outcome measure
1. Eccentric hamstring strength is measured using Hamstring Testing System (Nordboard) at baseline and week 9
2. 30 meter sprint is measured using speed recording system based on the light sensors (fitlight) at baseline and week 9
3. Vertical jump is measured using dual forceplate system (Vald Forcedecks) at baseline and week 9
4. Change of Direction (CoD) is measured using speed recording system based on the light sensors (fitlight) at baseline and week 9

Secondary outcome measures
Pain is measured using a Numerical Rating Scale after the intervention has performed (twice a week for 2 weeks then continue once a week for 6 weeks)

Overall study start date
01/06/2022

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Male football players
2. Aged 14-17 years
3. Active participation in the football academy

Participant type(s)
Healthy volunteer

Age group
Other

Lower age limit
14 Years

Upper age limit
17 Years

Sex
Male

Target number of participants
40

Total final enrolment
72

Key exclusion criteria
1. History of back and lower extremity injury (including hamstring) in the previous six months prior to the study
2. Specific eccentric strength training and specific sprint training more than one session per week in the previous six weeks prior to the study
3. Sustain injury during intervention period
4. Compliance < 75% of the total program
5. Absence in the pre- and/or-post test

Date of first enrolment
27/09/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
Indonesia

Study participating centre
Faculty of Sports Science, Universitas Negeri Yogyakarta
Jalan Colombo No.1 Karangmalang Yogyakarta
Yogyakarta
Indonesia
55281

Study participating centre
Faculty of Sports Science, Universitas Negeri Surabaya
Lidah Wetan
Kec. Lakarsantri
Kota Surabaya
Jawa Timur
Surabaya
Indonesia
60213

Study participating centre
Department of Orthopedic Surgery and Sports Medicine
Location AMC K1-208. Meibergdreef 9
Amsterdam
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1105 AZ

Sponsor information

Organisation
Ministry of Finance Republic of Indonesia

Sponsor details
Indonesia Endowment Fund for Education (Lembaga Pengelola Dana Pendidikan / LPDP)
Gedung Danadyaksa Cikini
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Sponsor type
Government

Website
https://lpdp.kemenkeu.go.id/en/

Funder(s)

Funder type

Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The results will be submitted for publication to an international, peer-reviewed journal, regardless of whether they will be positive, negative, or inconclusive in relation to the study hypothesis. The new knowledge will also be disseminated through websites, presentations, social media, and professional organizations (orthopedics and sports medicine, sports physiotherapists, athletic trainers, and public health).

Intention to publish date
01/12/2024

Individual participant data (IPD) sharing plan
Data are available upon reasonable request.
Data are deidentified participant data and it will be made available as soon as possible with publication. How to access data: m.i.zein@amsterdamumc.nl. Data will be shared, wherever legally and ethically possible an in line with ICMJE guidelines, with researchers who provide a methodologically sound proposal.

IPD sharing plan summary
Available on request