


# BMJ Open Study on Hamstring Re-injury Prevention (SHARP): protocol for an international multicentre, randomised controlled trial

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## ABSTRACT

**Introduction** Previous studies showed that the Nordic hamstring exercise (NHE) effectively prevents primary hamstring injury. However, no study investigated the secondary preventing effect of the NHE on hamstring reinjury. The primary purpose of this study is to investigate the effectiveness of the NHE for preventing hamstring reinjury after return to play (RTP) following a hamstring injury in football players. The secondary purpose is to determine the effect of the NHE on sprint and jump performance.

**Methods and analysis** This is an international multicentre, prospective, parallel-group randomised controlled trial study. Subjects include male or female football players aged 18–40 years and within 1 week of RTP following a hamstring injury will be randomised into Nordics or a control group. Subjects in both groups continue their regular football training, but the Nordics group will perform an additional NHE programme. An online questionnaire will be sent to the subjects in both groups once per week within the first 10 weeks, then continued at months 6, 9 and 12. In a (performance) substudy, we will evaluate the effect of the NHE on sprint and vertical jump performance at three time points (at the beginning of the study, after 10 weeks and 12 months of follow-up).

The primary outcomes are the incidence of hamstring reinjury within 2 and 12 months. The secondary outcomes are sprint and jump performance, adherence to the programme, duration of reinjury and reinjury burden.

**Ethics and dissemination** This study is approved by the medical ethics committee of Amsterdam University Medical Center (UMC) in the Netherlands (METC 2021\_117), Faculty of Medicine Universitas Gadjah Mada in Indonesia (KE/FK/1248/EC/2021), Norwegian School of Sport Sciences in Norway (number 216–270 122) and Denmark (ethical submission in process). The study's findings will be disseminated in scientific peer-reviewed journals and presented at international conferences.

**Trial registration number** NL9711.

## STRENGTH AND LIMITATIONS OF THIS STUDY

- ⇒ This study is the first international multicentre randomised controlled trial to evaluate the effectiveness of the Nordic hamstring exercise (NHE) for the secondary prevention of hamstring reinjury in football players with sufficiently large sample size.
- ⇒ The NHE used in this study is a familiar exercise to the athlete, and it can be easily performed with or without a partner.
- ⇒ Owing to the type of intervention, blinding the subjects is not possible.

## INTRODUCTION

Hamstring injury is the most common injury in football (soccer).<sup>1</sup> It represents 12%–14% of all football injuries and more than one-third of all muscle injuries.<sup>2,3</sup> The incidence of hamstring injury in elite football increased at the rate of 2.3% per year in the last two decades.<sup>4</sup> The most common injury mechanism is an eccentric stretch of the hamstring muscle during explosive movement such as sprinting, kicking or jumping.<sup>5–7</sup>

Hamstring injuries have a high incidence rate of reinjury.<sup>1,8</sup> More than half (59%) of hamstring reinjuries occur within 1 month after return to play (RTP).<sup>9,10</sup> The reinjury is generally associated with more severe symptoms and longer days to RTP than the initial injury.<sup>11</sup>

The injury commonly occurs during the excessive eccentric force applied to or required from the hamstring. Therefore, strengthening the hamstring muscle with eccentric training could potentially prevent the injury. Previous studies have shown that eccentric hamstring exercises have been proven to reduce the incidence of hamstring injuries.<sup>12–14</sup> Nordic hamstring exercise

(NHE) is known as one of the eccentric exercise methods widely used in football. Systematic reviews have shown that the NHE as part of an injury prevention programme or NHE-only programme can reduce primary hamstring injury rates up to 50% in football players.<sup>15 16</sup>

Despite its effectiveness in preventing hamstring injuries, no study specifically evaluated the NHE on reinjury prevention. Existing data on reinjury risk reduction are limited to Petersen *et al*,<sup>17</sup> which showed that a 10-week NHE programme performed during the seasonal break reduced hamstring injury risk by approximately 85% in subjects with the history of hamstring injury in the previous season. As the first month after RTP is the most vulnerable period for reinjury,<sup>10</sup> these results cannot be generalised to recommend the NHE intervention in-season directly after RTP. Therefore, it remains unknown whether the NHE intervention directly after RTP following hamstring injury can protect athletes from reinjury.

In addition to the preventive effect, there is emerging evidence that NHE may improve sprint and jump performance.<sup>18–20</sup> This has never been investigated in football players directly after RTP. Evaluating NHE's effect on performance is valuable as an additional consideration to coaches and football players in implementing the programme. Shamlaye *et al* showed that promoting the performance-enhancing effects can improve adherence to the injury prevention programme.<sup>21</sup>

The primary aim of this randomised controlled trial (RCT) is to assess the effect of the NHE performed after RTP following hamstring injury for preventing reinjury in football players. The secondary aim is to determine the effect of the NHE on sprint and jump performance. We hypothesise that NHE will reduce hamstring reinjury incidence at time points of 2 and 12 months after RTP following a hamstring injury and will improve sprint and jump performance.

## METHODS AND ANALYSIS

### Study design

This international multicentre, prospective, parallel-group RCT is designed in accordance with the Standard Protocol Items for Randomised Trials<sup>22</sup> and Consolidate Standards of Reporting Trials<sup>23</sup> guidelines. A flowchart of the study design and follow-up is shown in figure 1. Subjects will be randomly allocated into the Nordics group (NHE programme) or control (CON) group (regular football training only).

This trial is coordinated by Amsterdam University Medical Center (UMC) as the IOC Research Centre, in collaboration with Royal Netherlands Football Association (KNVB) and international participating centres. Presently, the international centres are (1) Oslo Sports Trauma Research Centre in Oslo, Norway; (2) Sports Orthopaedic Research Centre in Copenhagen, Denmark; and (3) Centre for Sports and Exercise Study Universitas Indonesia and Faculty of Sports Science Universitas Negeri Yogyakarta in Indonesia. Each study centre

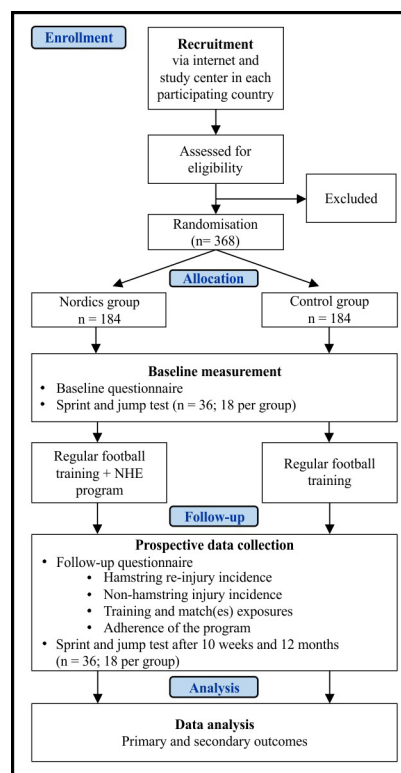


Figure 1 Flowchart of the study design and follow-up.

consists of research members with a national coordinator who conducts the study with a similar protocol as in the Netherlands. Adoption and language translation of the questionnaire, exercise instruction and promotion materials are performed to facilitate the data collection process in each study centre. The coordinating researcher, who is also the national coordinator of the Netherlands (MIZ), will arrange a periodical meeting with the other study centre to discuss the research progress. After the start of the study, other participation centres can still join. The collaboration structure of each centre is presented in figure 2.

The study was approved by the medical research ethics committee Amsterdam UMC in August 2021 and registered at Netherland Trial Register with an expected starting date in September 2021. The first patient in the Netherlands signed the consent form on 29 October 2021. Subjects' enrolment in each study centre has been conducted after the medical ethics in each country was approved, with the exception for Denmark which has yet to start (the ethical submission is still in the process). The recruitment is projected to be finalised in December 2023.

### Subjects

Three hundred and sixty-eight football players fulfilling the eligibility criteria will be included. Male and female football players aged 18–40 years and within 1 week after fully recovering from hamstring injury/RTP are eligible for inclusion.



**Figure 2** Collaboration structure of the study centres.

### Recruitment procedure

We will publicise the study and aim to recruit participants through the online media and our research partners. We will use the website (<http://sharponderzoek.nl>) and social media accounts such as LinkedIn, Twitter, Facebook and Instagram. We will also share the announcement with colleagues such as physiotherapists, physicians and football coaches using email and instant messenger.

In addition to those recruitment procedures, we will collaborate with football clubs, sports/physiotherapy clinics and national football associations as research partners. The research partners are asked to inform potential subjects about the study or directly contact the researcher if they find potential subjects. The online registration of the potential subjects can be done through the website. The registered participants will be checked for eligibility. The eligible participants will provide oral and written information about the study, and the consent form must be signed if they agree to participate.

Data collection for the sprint and jump performance substudy will be conducted in the research centres in the Netherlands and Indonesia. Subjects in these research centres will be asked to perform the sprint and jump tests until the required sample size is reached ( $n=36$ , 18 subjects per group).

### Randomisation, blinding and treatment allocation

This study consists of two randomisation groups (Nordics and CON groups), with equal weight (1:1). The randomisation will be performed using a computer-generated randomisation scheme, Castor. All researchers and study personnel other than the coordinating researcher will be blinded to group allocation. The subjects are asked not to communicate their group allocation or type of intervention to the other subjects or study staff. The unblinded researcher will manage the group allocation process and deliver the intervention to the subjects. The researchers will be unblinded only after the outcome analysis.

### Intervention

#### Nordics group

The Nordics group will perform the NHE in addition to their regular football training. The first 27 sessions of NHE will be performed within 10 weeks, and then it will be conducted once a week until 52 weeks of follow-up.

**Table 1** Nordic hamstring exercise protocol<sup>17</sup>

Week	Frequency, per week	Sets per training (n)	Reps per set
1	1	2	5
2	2	2	6
3	3	3	6–8
4	3	3	8–10
5–10	3	3	12–10–8 reps
11–52	1	3	12–10–8 reps

rep, repetition.

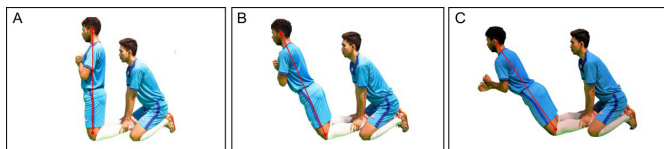
Thus, a full NHE intervention will consist of a total of 69 sessions (table 1).

The instruction manual of the NHE programme will be provided for the Nordics group. The manual explains the details of the NHE programme using pictures, descriptive texts, tables and video (<https://www.youtube.com/watch?v=Ypn8ezkKsg&t=337s>). The subjects will be instructed to perform the NHE independently without direct supervision from the research team. If the subjects have any questions regarding the programme, they can contact the national coordinator of the study centre via email or telephone.

The NHE can be performed with or without a partner.

Alternative 1 (with a partner, figure 3)<sup>17</sup>: The subjects start kneeling on the soft surface with their torso from the knees upward held rigid and straight. A partner applies pressure to the subject's heels or lower legs to ensure that the feet stay in contact with the ground throughout the movement. The subjects are then asked to lean forward and counteract the forward falling motion to go as forward/low as possible using the hamstrings but without the help of hands or arms. When the subjects can no longer counteract the falling, they can use their arms and hands to buffer the fall, let the chest touch the surface and get back to the starting position by pushing with their hands to minimise hamstring loading in the concentric phase.

Alternative 2 (without a partner, figure 4): The exercise concept is similar to the standard NHE, but the fixed equipment replaces the partner's role. The subjects are asked to hook their feet underneath fixed equipment (it can be a bed, cable pull-down machine, a nautilus machine or anything else with an opening a few inches off the ground) and to kneel on the soft surface. The subjects are then asked to lean forward and counteract the forward falling motion to go as forward/low as possible using the hamstrings but without the help of hands or arms. When the subjects can no longer counteract the falling, they can use their arms and hands to buffer the fall, let the chest touch the surface and get back to the starting position by pushing with their hands to minimise hamstring loading in the concentric phase.



**Figure 3** Nordic hamstring exercise with partner. (A) Start, (B) midpoint and (C) end. The red line indicates that the subject's torso from the knees upward must be straight.

### CON group

The CON group will perform their regular football training. To capture real-world situations, the subjects in the CON group can continue their self-initiated injury prevention programme, including NHE. Previous studies showed a low implementation of NHE in football players (only 4% at amateur level and 6.7% at professional level),<sup>24 25</sup> so we expect that NHE 'contamination' in the CON group will most likely be limited. The follow-up questionnaire will be used to monitor the details of their self-initiated programme.

### Data collection procedure

#### Questionnaires

Except for the performance tests, all data will be collected using online-based questionnaires. The subjects will complete a baseline questionnaire at the beginning of the study. Subsequently, they will complete a follow-up questionnaire once a week for the first 10 weeks and at months 6, 9 and 12 of follow-up. In total, the subjects will receive 14 questionnaires during the study. The researcher will remain in contact (by telephone, email or instant messengers) to remind them to complete the questionnaire.

#### Sprint and jump tests

The sprint and jump performance tests (n=36) will be performed in the Netherlands and Indonesia at three time points (at the beginning of the study, after 10 weeks and after 12 months) at their football club or the facilities near the research centre.

The 30 m sprint test has acceptable validity and reliability to assess sprinting skills in football players.<sup>26</sup> The speed recording system based on the photocell sensors in the Netherlands (Micro gate witty timer, ProCare BV, the Netherlands) or the light sensors in Indonesia (Fitlight, USA) are set at the starting line and at the 30 m finish line. This technology has been used in previous studies, and it is a recommended technology to record sprint results in scientific research with good validity and reliability.<sup>27 28</sup>



**Figure 4** Nordic hamstring exercise without partner. (A) Start (subjects hook their feet underneath the foosball table (fixed equipment)), (B) midpoint and (C) end. The red line indicates that the subject's torso from the knees upward must be straight.

The subject will start from a static upright position, with their front foot positioned 1 m behind the first pair of sensors (start line). The subjects will be instructed to run at the maximum speed to the final pair of sensors at the finish line (30 m).<sup>29 30</sup> The subject will be given three trials to perform the test, and the best time (in seconds) will be used for analysis.

The vertical jump test will measure the jump performance. This study will perform two types of vertical jump, namely, squat jump (SJ) and countermovement jump (CMJ). These two types of vertical jumps have the greatest reliability compared with other jumping tests.<sup>31</sup> For the SJ test, the subjects will be instructed to start the jump in a position of 90° knee flexion with the feet shoulder-width apart and their hands on their hips. Subjects will be asked to jump as high as possible while maintaining their hands on their hips.<sup>32</sup> For the CMJ test, the subjects will start in a standing position with a straight torso and knee fully extended with the feet shoulder-width apart. Subjects will be asked to keep their hands on their hips throughout the whole jump. They will be instructed to perform a quick downward movement (approximately 90° of knee position) and afterward a fast-upward movement to jump as high as possible.<sup>33</sup> Both of the jumps will be recorded with video on a smartphone and analysed by a validated application (My Jump 2).<sup>34</sup> Jump height will be recorded on the tool in centimetre. The subjects will be given three trials to perform these vertical jump tests. The highest score on each jumping test will be taken into analysis. The overview of data collection of the outcome measures can be found in [table 2](#).

### Outcome measure

#### Baseline data

The subjects will complete the baseline questionnaire at the beginning of the study, which consists of (1) subject characteristics: age (year), sex (male/female), weight (kg), height (metre), competition level (amateur/recreational, semiprofessional and professional) and dominant leg (right, left or both); (2) history of injury and rehabilitation: date of hamstring injury (day/month/year), side of injury (right/left), mechanism of injury (sprinting/non-sprinting), history of hamstring exercise or any injury prevention programme (no/if yes, name of the programme and the frequency-set-repetition), history of NHE during the rehabilitation process (no/if yes, the total number of sessions), history of hamstring injury (no/if yes, mention the number of injuries in both legs, the number of injury in the same leg and the date of hamstring injury in the same leg), total number of rehabilitation sessions with the physical therapist until RTP, total rehabilitation sessions with the athletic trainer/sports therapist/rehabilitation coach/strength and conditioning coach; and (3) psychological readiness to RTP and subject's reinjury risk estimation: perceived recovery (0=not recover at all, 100=completely recovered), chance to sustain a hamstring reinjury (0=definitely reinjury, 100=definitely not reinjury), chance to sustain another

**Table 2** Overview of data collection of the outcome measures

Timeline	Week 0		Weeks 1–10		Week 11	Week 11–52			Week 53	
	Baseline data collection	Performance test (pretest)	Intervention	Weekly questionnaire	Performance test (post-test I)	Intervention	Month 6	Month 9	Month 12	Performance test (post-test II)
Subject's activity	Fill out the questionnaire.	Sprint and jump tests	Performing group-oriented instruction (NHE based on the schedule for the Nordics group)	Fill out the questionnaire	Sprint and jump tests	performing group-oriented instruction (Nordics group: Continue with the NHE programme once a week)	Fill out the questionnaire	Fill out the questionnaire	Fill out the questionnaire	Sprint and jump tests
Location	Online	Football field	In the subject's own place	Online	Football field	In the subject's own place	Online	Online	Online	Football field
Estimated time/duration	5 min	30 min	5 min per session for Nordics group (maximum three times per week)	5 min per questionnaire	30 min	5 min per session (Nordics group)	5 min	5 min	5 min	30 min
Performance study in the Netherlands and Indonesia (n=36). NHE, Nordic hamstring exercise.										

non-hamstring injury (0=definitely sustain another injury, 100=definitely not sustain another injury).

### Primary outcome

The primary outcome is the incidence of hamstring reinjury within 2 and 12 months after RTP. The subjects will report if they sustain any hamstring injuries during a 12-month period via an online follow-up questionnaire. The definitions in this study follow the recommendation by the football injury consensus group.<sup>35</sup> Hamstring injury is defined as ‘any acute occurring physical complaint in the region of the posterior thigh sustained during a football match or training, irrespective of the need for medical attention or time-loss from football activity’.<sup>35</sup> Hamstring reinjury is defined as ‘acute occurring physical complaint in the region of the posterior thigh of the same type and the same site as the index injury and which occurs after the player’s return to full participation from the index injury, resulted in missed training/match’.<sup>35</sup>

### Secondary outcomes

#### *Adherence and exposure*

The online follow-up questionnaire will record the adherence to the NHE programme in the Nordics group, including the frequency, repetition, set, side effects of exercise and the reason when they miss exercising (no time, no motivation, injury, sickness or other). In the CON group, the researcher will monitor the type and the exercise programme if they have a self-initiated injury prevention programme in their routine training, including the NHE. Any complaints after performing the programme will be asked using open-ended questions in both groups.

The frequency (number of sessions per week) and duration (in minutes) of match and training sessions in the groups will also be monitored using a follow-up questionnaire. Match exposure is defined as the play between teams from different clubs.<sup>35</sup> Training exposure is defined as team-based and individual physical activities under the control or guidance of the team’s coaching or fitness staff to maintain or improve players’ football skills or physical condition.<sup>35</sup> The subjects will also be asked to report the reason if they do not attend the training or matches.

#### *Sprint and jump performance test results*

Data on sprint (second) and jump (centimetre) tests from the selected subjects will be included for preintervention–postintervention analysis to investigate the effect of the NHE programme on sprint and jump performance.

#### *Non-hamstring injury incidence*

The non-hamstring injury incidence will be recorded based on the body part (head and neck, upper extremity, trunk and lower extremities), side of injury (right or left) and classification of injury (acute or chronic) during 12 months’ follow-up period. Injury is defined as any physical complaint sustained by a player that results from a football match or football training, irrespective of the need for medical attention or time loss from football activities.<sup>35</sup>

#### *Duration of reinjury (time loss) and reinjury burden (IB)*

The duration of reinjury is defined as the number of days between reinjury until RTP, in which RTP is defined as ‘the moment players return to full, unrestricted training or match’.<sup>35</sup> These absence days will be recorded by a follow-up questionnaire and used to calculate the re-IB. Re-IB is defined as the number of reinjury days lost per 1000 hours of football exposure.<sup>36</sup>

### Sample size

The primary outcome measure hamstring reinjury will be evaluated at 2 and 12 months. Based on a previous study in primary hamstring prevention, we consider the NHE intervention to be clinically relevant when it will lead to an expected 70% reduction of the hamstring reinjury compared with the CON group.<sup>17 37 38</sup>

For the 2 months’ evaluation, based on reinjury reduction with two-sided testing, a significance level of 0.05 and power of 0.9, an estimated dropout rate of 10% and reinjury prevalence of 15%,<sup>39</sup> we calculate 368 subjects will need to be recruited (184 subjects each group). As the reinjury prevalence is expected to increase up to 30% at 12 months’ follow-up,<sup>40</sup> the calculated sample size of 368 subjects is more than sufficient for the 12 months’ reinjury analysis.

For the sprint and jump performance substudy, we expect a 4% sprint<sup>19 41</sup> and 7% vertical jump<sup>18 20 42</sup> improvement in the Nordics group compared with the CON group. Accepting 80% statistical power with a significant level of 0.05, SD of 0.05 for sprint and 3 cm for vertical jump, and an estimated dropout rate of 10%, we calculate that 36 subjects will need to be recruited (18 subjects each group).

### Data management and protection

All data will be coded and stored in the Castor, an online clinical data management platform that meets the Amsterdam UMC (location AMC) safety criteria and good clinical practice guidelines. All data gained outside Castor (eg, sprint and jump test results) will be stored on the Amsterdam UMC (location AMC) secured hard drive. The investigators will safeguard the coded data through password-secured access. All participants data will be archived for at least 15 years and handled with in accordance with the General Data Protection Regulation/Algemene Verordening Gegevensbescherming. Data protection is provided through the safety protocol of Castor Electronic Data Capture with automated backups and Secure Sockets Layer (SSL) security.

### Monitoring

The monitoring committee in each international study centre depends on the country’s regulations. In the Netherlands, the Clinical Monitoring Center of Amsterdam UMC will monitor this study. As this study is categorised as ‘negligible risk’, monitoring for this study will only occur during one site visit. In Norway, the Norsk Senter for Forskningsdata will monitor the study in the second year

and by the end of the study period. In Indonesia, a formal data monitoring committee is not needed due to the low risk to the participants and lack of conflicting interests.

### Statistical methods

Statistical analysis will be performed using SPSS V.25.0. All *p* values are two-sided and set at <0.05. Descriptive statistics will be conducted to describe baseline data (subjects' characteristics, history of rehabilitation, psychological readiness for RTP and self-reinjury risk estimation), training and matches exposure, and non-hamstring injury report in both groups. If the data are not normally distributed, the data will be presented as mean and SD or median and IQRs.

The hamstring reinjury incidence (1) will be calculated according to the formula  $i=n/e$ , where *n* is the number of hamstring reinjuries during the study period, and *e* is the sum of exposure time expressed in the player match, training or total hours. The result will be multiplied by 1000 to obtain the rate per 1000 playing hours. The rate ratio will be calculated by dividing the incidence rate into the Nordics and CON groups to compare the risk of hamstring injury in the two groups.

Time to event analysis will be performed by calculating the Hazard Ratio (HR) using a Cox regression model. In this model, the dependent variable is the time (days) from RTP to the event (reinjury) or the end of the follow-up. Subjects who sustain another injury causing absence from football training and matches for more than 4 weeks (eg, Anterior Cruciate Ligament/ACL rupture) during follow-up will be censored at the time of the injury. Subjects lost to follow-up or withdrawn from this study will be censored at the time of their last follow-up. Subjects without training and match exposure data on the 3-monthly questionnaire (at the 6th, 9th and 12th months of follow-up) will be censored at the time of their last follow-up. Subjects completing their 12-month follow-up will be censored at the time of the last follow-up. We will use one minus survival plots based on the Cox regression to evaluate the reinjury prevention effects of the NHE in the Nordics group compared with the CON group.

Repeated analysis of variance is used for the performance test outcomes to compare the mean of before versus after one and two intervention results in the same group (Nordics group and CON group). The general linear model test will be conducted to analyse before versus after intervention differences between Nordics and CON groups. The non-parametric tests (Friedmann and Mann-Whitney) are used as non-parametric tests if the data distribution is not normal. Normality test will be performed using Kolmogorov-Smirnov or Shapiro-Wilk test.

We will use a multiple regression with backward elimination method. Adjustments will be made for those baseline variables that are associated with the primary outcome, with a *p* value of <0.10.

The hamstring re-IB and corresponding 95% CI will be calculated by the total number of days lost to hamstring reinjury per 1000 hours of football exposure (training and matches). To assess the effect of NHE on IB, we will compare the IB between Nordics and CON groups.

Adherence to the programme is calculated based on the questionnaire results. The complete NHE programme consists of 69 sessions (27 sessions in the first 10 weeks, then continuing once a week until 52 weeks). Adherence rate calculation will be done using this formula: amount of NHE sessions/total NHE session×100%= % adherence.

### Patient and public involvement

The patient and the public are not involved in the study design, execution and analysis phases. Dissemination activities will include events (seminars, conferences or workshops) enabling the patient to attend and social media strategy with the patient and public involvement to share the new knowledge from this study.

### COVID-19 safety protocol

In response to the pandemic, this study will be conducted with the COVID-19 safety protocol. The majority of the research procedures can be executed without any direct contact, so the risk of COVID-19 transmission will be reduced. The online meeting, telephone and document transfers via post will be conducted as alternative correspondence strategies. The only direct measurement in this study is the sprint and jump performance tests in the selected subject. The tests will be performed with the COVID-19 safety protocol, such as arranging the appointment when the subjects are in healthy condition, arranging the test schedule to avoid mass gathering at one time, physical distancing, wearing a face mask, and maintaining personal and equipment hygiene.

### ETHICS AND DISSEMINATION

This study is approved by the medical ethics committee in four countries: Amsterdam UMC in the Netherlands (METC 2021\_117), Faculty of Medicine Universitas Gadjah Mada in Indonesia (KE/FK/1248/EC/2021), Norwegian School of Sport Sciences in Norway (number 216–270122) and Denmark (ethical submission in process). The study was registered in the Dutch Trial Register as the Study on Hamstring Re-injury Prevention. Any important protocol amendments or other changes will be reported to the medical ethics committee of the Amsterdam UMC and communicated in the RCT report.

All participants receive oral and written information following the Helsinki Declaration. Written consent is collected from all participants by the coordinating researcher before the intervention start. The personal information of the participants will be used confidentially before, during and after the study.

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 organisations (orthopaedics and sports medicine, sports physiotherapists, athletic trainers and public health).

Authorship eligibility will be in line with the recommendations of the International Committee of Medical Journal Editors.

## DISCUSSION

This study is the first study to evaluate the effectiveness of the NHE for preventing reinjury directly after RTP following a hamstring injury. It will potentially contribute to the beneficial effect on health, medical cost and performance in football players. The result will provide scientific evidence and support for coaches, athletes and healthcare providers to prevent hamstring reinjury.

A study from McKay *et al* suggested that additional motivational factors should be considered to improve the programme's adherence.<sup>43</sup> As identified in a Dutch prevention trial on uninjured athletes, personal motivation was a key parameter for non-compliance to the programme.<sup>24</sup> In this study, we expect that the postinjured athletes have additional motivation to prevent reinjury, resulting in higher adherence to the NHE programme than the uninjured subjects in the primary injury prevention studies. We will also investigate the NHE's effect on sprint and jump performance. The results of this investigation can be used to consider NHE implementation related to the injury prevention effect and performance.

In this study, subjects in the CON group are allowed to continue their self-initiated injury prevention programme, including NHE. Although their volume (frequency, set and repetition) may be different from the standard protocol in the Nordics group, it could potentially become a confounding factor. A systematic review by Cuthbert *et al* showed that both high-volume and low-volume NHE interventions positively affect hamstring eccentric strength improvement, which contributes to preventing injury.<sup>44</sup> However, previous studies also showed that the implementation of NHE in football players is very low,<sup>24 25</sup> so we expect this will be limited to the confounding factor. The follow-up questionnaire will closely monitor the use of NHE and/or other preventive interventions in both groups.

This study uses methodology and terminology consistent with the consensus statement on injury definition in football to compare the result with other studies.<sup>35</sup> Data collection will be conducted by online-based registration to minimise data loss and data modification. All procedures in this study will be executed with the COVID-19 safety protocol to reduce the risk of COVID-19 transmission.

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