Preventing ankle sprain recurrences in sports
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2010

document version
Publisher's PDF, also known as Version of record

Link to publication in VU Research Portal

citation for published version (APA)
Hupperets, M. D. W. (2010). Preventing ankle sprain recurrences in sports: athletes back in balance?.

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Effect of unsupervised home based proprioceptive training on recurrences of ankle sprain: randomised controlled trial

Hupperets MDW, Verhagen EALM, van Mechelen W. Effect of unsupervised home based proprioceptive training on recurrences of ankle sprain: randomised controlled trial. BMJ 2009; 339: b2684
ABSTRACT

Objective To evaluate the effectiveness of an unsupervised proprioceptive training programme on recurrences of ankle sprain after usual care in athletes who had sustained an acute sports related injury to the lateral ankle ligament.

Design Randomised controlled trial, with one year follow-up.

Setting Primary care

Participants 522 athletes, aged 12-70, who had sustained a lateral ankle sprain up to two months before inclusion; 256 athletes (120 female and 136 male) in the intervention group; 266 athletes (128 female and 138 male) in the control group.

Intervention Both groups received treatment according to usual care. Athletes allocated to the intervention group additionally received an eight week home based proprioceptive training programme.

Main outcome measure Self reported recurrence of ankle sprain.

Results During the one year follow-up, 145 athletes reported a recurrent ankle sprain: 56 (22%) in the intervention group and 89 (33%) in the control group. Nine athletes needed to be treated to prevent one recurrence (number needed to treat). The intervention programme was associated with a 35% reduction in risk of recurrence. Cox regression analysis showed significantly fewer recurrent ankle sprains in the intervention than in the control group. This effect was found for self reported recurrent ankle sprains (relative risk 0.63, 95% confidence interval 0.45 to 0.88), recurrent ankle sprains leading to loss of sports time (0.53, 0.32 to 0.88), and recurrent ankle sprains resulting in healthcare costs or lost productivity costs (0.25, 0.12 to 0.50). No significant differences were found between medically treated athletes in the intervention group and medically treated controls. Athletes in the intervention group who were not medically treated had a significantly lower risk of recurrence than controls who were not medically treated.

Conclusions The use of a proprioceptive training programme after usual care of an ankle sprain is effective for the prevention of self reported recurrences. This proprioceptive training was specifically beneficial in athletes whose original sprain was not medically treated.

Trial registration ISTRCN34177180
Chapter 3 Effectiveness of the intervention

INTRODUCTION
Regular participation in physical activity and sports is beneficial for health. However, there is also an increased risk to sustain injury, of which ankle sprains are the most common in many sports.

Each day an estimated 23,000 ankle sprains occur in the United States, equalling about 1 sprain per 10,000 people per day. The most recent count of sports injuries in the Netherlands (2002-3) estimated an annual total of 1,300,000 acute sports injuries, of which 234,000 were ankle sprains. Of these, 110,000 (47%) required some form of medical treatment. Recent research showed that, in the Netherlands, the mean total costs (direct and indirect) of one ankle sprain was approximately €360 (£308, $507), giving an estimated annual cost of €84,240,000 in the Netherlands alone. In addition, there is strong evidence that in the year after injury, athletes have twice the risk of a recurrent ankle sprain. Up to half of these ankle sprain recurrences result in chronic pain or instability, potentially leading to disability and prolonged medical care.

The high rate of ankle sprains across all sports, as well as the severity and subsequent negative consequences of ankle sprains on future sports participation motivates preventive measures.

A preventive effect of various measures has been found only for athletes with previous ankle sprains. A primary preventive effect of tape, braces or proprioceptive training has yet to be established. The dynamic recursive model of sport injury creates insight in the aetiology of ankle sprain recurrences. After an index ankle sprain, the athlete’s intrinsic risk factors are altered, resulting in an increased predisposition to re-injury.

Although treatment of ankle sprain aims at recovery, it does not seem to lower the increased risk of re-injury. This hypothesis is substantiated by secondary analyses of a preventive trial in top-level volleyball athletes. After the introduction of a proprioceptive training programme ankle sprain recurrences were reduced by 50%, and over 90% of the previously injured
Preventing ankle sprain recurrences in sports athletes back in balance?

athletes completed a full rehabilitation programme for their index ankle sprain.
This finding added to the already available literature warrants the prolongation of usual care with additional preventive efforts to effectively prevent recurrences of ankle sprain. We evaluated the effectiveness of an individual home based proprioceptive training programme after rehabilitation and treatment by usual care to prevent ankle sprain recurrences. It was hypothesized that, in line with recent research on the effect of preventive measures, a 50% reduction in ankle sprain recurrence risk could be established through proprioceptive training.

METHODS
The randomised controlled trial had a follow-up of one year, chosen because the increased risk for ankle sprain recurrences seems to exist only during the first year after injury. Athletes were randomised to intervention or control, with stratification for sex, type of enrolment, and usual care of ankle sprain. A statistician who had no knowledge regarding any other characteristics of the participants performed the randomisation. Box 1 provides details of the procedure used to recruit athletes.
Athletes were recruited from August 2006 to August 2007 through medical channels (11 emergency rooms, five general practices, and four physical therapy offices) throughout the Netherlands and non-medical channels (through adverts in newspapers, sports magazines, sports tournaments and on the internet). All were active sports participants aged 12-70 who had sustained an ankle sprain in the preceding two months.
Before inclusion, a physical therapist contacted each injured athlete by phone and conducted a thorough oral assessment of the reported ankle sprain using an injury registration questionnaire, derived from a previously used injury registration form. This included questions on diagnosis, cause, and aetiology of the injury. If the injury had been medically
treated, the advised treatment and the exact profession of who treated the injury were recorded with the diagnosis provided. All participants received treatment according to usual care, defined as any form of rehabilitative treatment used by the athlete, without interference from the authors. Athletes allocated to the intervention group were informed that they would receive an eight-week proprioceptive training programme, preferably starting immediately after inclusion but not before the end of rehabilitation with usual care and re-participation in sports.

**Intervention**

The programme was derived from a previously described programme\textsuperscript{12}, modified by two physical therapists to consist of more general exercises that were to be carried out individually. Feasibility was tested in a pilot study. A detailed description of the different basic exercises of the proprioceptive training programme is described elsewhere,\textsuperscript{26} and the training programme is in the appendix on bmj.com. The programme prescribed three training sessions a week, with a maximum duration of 30 minutes a session. Athletes were encouraged to perform the exercises as part of their normal warm up. Exercises gradually increased in difficulty and training load during the eight-week programme. Athletes in the intervention group received a balance board (Avanco AB, Sweden), exercise sheets, and an instructional DVD showing all exercises of the programme. All information was also provided on a website, only accessible for those in the intervention group.

**Outcome measures**

The outcome was incidence density of ankle sprain and its 95% confidence interval, expressed as incident ankle sprains per 1,000 hours of exposure. We differentiated self reported sudden inversions of the same ankle according to severity\textsuperscript{27}: (1) recurrences leading to loss of sports time; (2) recurrences resulting in health care costs or lost productivity costs or both.
Exposure and injury registration

During the one year follow-up, athletes reported recurrences and details of their sports participation for each training session and match on a monthly basis. Athletes who reported a recurrence completed a web based questionnaire similar to the injury registration form that was completed orally before inclusion. Athletes who had sustained a recurrence also received a cost-diary that registered all healthcare costs and costs due to loss of productivity from the moment of injury until full recovery.

Athletes in the intervention group self rated compliance after four weeks and eight weeks of training. To rule out spill over or contamination between groups, every month we asked those in the control group whether they had participated in proprioceptive training during the past month.

On the basis of the completed injury registration forms, a physical therapist and the primary researcher, who were blinded to group allocation, independently rated all registered ankle injuries as acute lateral ankle sprains or other ankle injuries. There was agreement on all independently assessed injury registrations. The box gives the definitions used to register ankle sprain recurrences. A similar method of injury registration and diagnosis was used previously in other studies.12,28

Sample size

We considered a difference of 50% in the incidence of recurrent ankle sprains between the groups after one year to be clinically relevant.12 With a prevalence of recurrent ankle sprain being about 13% in one year9, we needed 275 people per group to detect the intended difference of 50% in the incidence of recurrences, with a power of 80% and an α of 5%. Assuming a dropout rate of about 20%, we needed 688 athletes to detect a potentially clinically relevant effect.
Statistical methods

All statistical analyses were undertaken according to a pre-specified plan. Injury incidences and corresponding 95% confidence intervals were calculated for total sports participation as the number of recurrent ankle sprains reported per 1,000 hours of sports, with exposure time of each individual player until the first recurrent ankle sprain. We also carried out a subgroup analysis on medical care utilization for the inclusion ankle sprain.

Cox regression analysis compared risk of recurrence of ankle sprain between the groups, with adjustment for age, type of sport (i.e. contact or non-contact), and level of sports (i.e. competitive or recreational). Other variables were checked for confounding or interaction, but none was found. All analyses were carried out according to the intention to treat principle. Differences were considered significant at P<0.05.
Compliance numbers were presented as the absolute number of athletes (and percentages) in each category. Athletes in the control group who performed some form of proprioceptive training during follow-up were presented as a total number and a percentage of the total number of athletes in that group.

RESULTS
We recruited 522 athletes, 351 (67%) through medical channels and 171 (33%) through non-medical channels. Stratification ensured equal numbers for key factors in the intervention (n=256) and control group (n=266), and at baseline there were no significant differences between groups (table 1). The figure shows the flow of participants through the study. The dropout rate was similar between groups. Five out of 266 athletes in the control group (2%) reported performing some sort of proprioceptive training exercises during follow-up.

Exposure and injury characteristics
Participants took part in 30,140 hours of sports in the intervention group and 30,682 hours in the control group. During the one year follow-up, 145 (28%) reported a recurrent ankle sprain: 56/256 (22%) in the intervention group and 89/266 (33%) in the control group.

The overall incidence of ankle sprain per 1,000 hours of sports was 1.86 (95% confidence interval 1.37 to 2.34) in the intervention group and 2.90 (2.30 to 3.50) in the control group (table 2).

Effect of proprioceptive training programme
Cox regression analysis showed that the risk of self reported recurrences of ankle sprain was significantly lower in the intervention group than in the control group (relative risk 0.63, 95% confidence interval 0.45 to 0.88, table 2). Similarly, significant lower relative risks were found for the intervention athletes for time loss (0.53, 0.32 to 0.88) costs (0.25, 0.12 to
Our results show that nine athletes needed to be treated to prevent one ankle sprain recurrence. Furthermore, the programme led to a 35% relative risk reduction in the intervention group.

Table 1 Athlete characteristics, given as mean (standard deviation) or percentage.

|                      | Intervention       | Control          |
|----------------------|--------------------|------------------|
| N                    | 256 (m=136; f=120) | 266 (m=138; f=128) |
| Age (years)          | 28.6 (11.8)        | 28.0 (11.6)      |
| Weight (kg)          | 73.4 (13.3)        | 71.7 (13.0)      |
| Height (cm)          | 176.9 (9.9)        | 177.4 (9.5)      |
| Experience (years)   | 10.82 (8.8)        | 10.75 (8.0)      |
| Sports exposure (hours) | 117.73 (93.59)  | 115.35 (113.51) |

Usual care
- Medical 171 (49%) 180 (51%)
- Non-medical 85 (50%) 86 (50%)

Ankle sprain history
- Index 120 (47%) 124 (47%)
- Last recurrence < 12 months ago 54 (21%) 62 (23%)
- Last recurrence > 12 months ago 82 (32%) 80 (30%)

Ankle protective devices
- Brace 47 (18.1%) 62 (23.0%)
- Tape 73 (28.2%) 64 (23.8%)
Figure 1 Flowchart of the prospective intervention trial.
Chapter 3 Effectiveness of the intervention

Effect on medically treated athletes
Cox regression subgroup analysis was carried out for ankle sprains that included medical treatment during usual care at time of inclusion. Within this subgroup, we found an intervention effect only for recurrences leading to costs (0.24, 0.08 to 0.72, table 3). We found no differences for self reported recurrences (0.89, 0.54 to 1.45) and recurrences leading to loss of sports time (0.62, 0.30 to 1.30).

Effect on non-medically treated athletes
Cox regression analysis showed that the intervention group athletes who reported non-medical treatment of their ankle sprain had a significantly lower risk of recurrence than controls. This effect was found for self reported recurrences (0.45, 0.28 to 0.72), for recurrences leading to loss of sports time (0.47, 0.23 to 0.96), and for ankle sprain recurrences leading to costs (0.25, 0.10 to 0.61).

Compliance with the programme
A total of 58 (23%) athletes in the intervention group said they had fully complied with the eight week proprioceptive training programme; 75 (29%) said they had been partially compliant; 89 (35%) were classified as not compliant. Compliance to the training programme was unknown for 34 (13%) athletes as they did not complete the questionnaires. Five out of 266 in the control group (2%) said they had performed some sort of proprioceptive training exercises during the one year follow-up. These athletes performed proprioceptive training exercises as part of medical treatment of a recurrence of ankle sprain and were not incorporated in the analysis.
### Table 2: Injury incidence (95% confidence interval) and Relative Risk (RR) given by injury severity perspective.

| Ankle sprain         | Intervention | Control | RR   |
|----------------------|--------------|---------|------|
|                      |              |         |      |
| Self-reported        | 1.86         | 2.90    | 0.63 |
|                      | (1.37 to 2.34)| (2.30 to 3.50)| (0.45 to 0.88)|
| Time loss            | 0.65         | 1.17    | 0.53 |
|                      | (0.38 to 0.92)| (0.82 to 1.52)| (0.32 to 0.88)|
| Leading to costs     | 0.29         | 1.08    | 0.25 |
|                      | (0.11 to 0.47)| (0.74 to 1.42)| (0.12 to 0.50)|

RR was derived from Cox regression adjusted for age, type of sport, and level of sports.

### Table 3: Injury incidence (95% confidence interval) and Relative Risk (RR) given by injury severity perspective and inclusion ankle sprain treatment.

| Ankle sprain         | Intervention | Control | RR   |
|----------------------|--------------|---------|------|
|                      |              |         |      |
| Self-reported        |              |         |      |
| Medical treatment    | 2.02         | 2.12    | 0.89 |
|                      | (1.28 to 2.75)| (1.42 to 2.83)| (0.54 to 1.45)|
| Non-medical treatment| 1.71         | 3.79    | 0.45 |
|                      | (1.07 to 2.36)| (2.78 to 4.80)| (0.28 to 0.72)|
| Time loss            |              |         |      |
| Medical treatment    | 0.65         | 1.13    | 0.62 |
|                      | (0.26 to 1.03)| (0.66 to 1.60)| (0.30 to 1.30)|
| Non-medical treatment| 0.65         | 1.22    | 0.47 |
|                      | (0.27 to 1.03)| (0.70 to 1.75)| (0.23 to 0.96)|
| Leading to costs     |              |         |      |
| Medical treatment    | 0.23         | 1.18    | 0.24 |
|                      | (0.00 to 0.46)| (0.69 to 1.67)| (0.08 to 0.72)|
| Non-medical treatment| 0.35         | 0.97    | 0.25 |
|                      | (0.07 to 0.62)| (0.51 to 1.43)| (0.10 to 0.61)|

RR was derived from Cox regression adjusted for age, type of sport, and level of sports.
DISCUSSION

An unsupervised home-based proprioceptive training programme given in addition to usual care is effective in reducing the incidence of recurrent ankle sprains in athletes. In line with our hypothesis, we found a twofold reduction in risk of recurrence for self recurrences. We found the same effect for time loss because of recurrences. Other proprioceptive training trials have recently shown a reduction in the incidence of ankle sprain recurrence.12,13 Ankle sprains leading to costs were 3.6 times higher in control athletes than in intervention athletes. There are no comparative data available for recurrences leading to costs.

Study limitations

We used self report for recording the initial ankle sprain, for which athletes were included in the study, and for recurrent ankle sprains during the study. As recurrences were reported on a monthly basis, recall bias was not likely. Misclassifications of injuries (such as faulty diagnosis of acute lateral ankle ligament sprains) sustained during the follow-up, however, was possible. To minimise misclassification errors, we adapted registration forms from those used recently in a randomised trial in which self report was used for the registration of ankle injuries.12 All recorded injuries to the ankle were blinded for group assignment and independently diagnosed by two sports physicians as being acute lateral ankle ligament sprains or other ankle injuries. Both physicians agreed on all injuries. Furthermore, the method of registering injuries by self report was similar to that used in a recent cluster randomised controlled trial on the prevention of injuries in young female footballers.28 All self reported recurrent ankle sprains were registered as re-injuries. Although these sprains were mostly described as being mild and leading to short term discomfort, they could be classified as subjective sensations of giving way.29 These sensations are well known to occur in individuals with functional ankle instability.
Loss to follow-up, at 14%, was considerably lower than the expected 20%. Baseline variables of athletes that were lost to follow-up did not differ significantly from the other athletes. Therefore, we believe that bias because of selective drop-out was limited.

**Relation to other studies**
To date, only one randomised controlled trial has studied the effect of a rehabilitative training programme on recurrence of ankle sprain after an acute ankle ligament sprain. A year after injury, that study found a significant difference in re-injuries in favour of the intervention group. The study sample size, however, was low compared with that in our study (92 v 522), considerable more athletes were lost to follow-up (27% v 14%), and information on re-injuries was collected retrospectively a year after the acute ankle sprain. Whereas exercises in the trial by Holme et al. were supervised by physical therapists, we used an unsupervised training programme.

**Data validation**
We recruited athletes from all ages, all levels of sports, different types of treatment, and from large geographical regions of the Netherlands, so the external validity was high. Furthermore, as we found no differences between groups at baseline, in dropout rates, and in exposure during the study, the internal validity was also high. By using standard injury registration forms that were judged by two researchers independently, we assume that reliability and validity was ensured given our experience in a previous comparable study. Thus reliability for comparing the data between the intervention and the control groups was ensured.

**Compliance**
Although we found a significant reduction in the risk of ankle sprain recurrence, a higher compliance to the training programme could have
resulted in more pronounced differences between the groups. Compliance with the training programme was measured with a monthly compliance questionnaire. As direct contact with the individual athlete was impossible, this was the only option of monitoring compliance. At least six weeks of proprioceptive training seem necessary to reduce re-injury risk\textsuperscript{18}, so partial compliance to the present training programme was probably insufficient to induce preventive effects.

\textit{Generalizability}

Since the intervention was implemented for both sexes, all ages, all types of sports, and at different levels of sports, the results indicate that the entire range of athletes, from young elite to intermediate and recreational senior athletes, would benefit from using the presented training programme for the prevention of recurrences of ankle sprain. By including non-medically treated and medically treated athletes, we covered a broad spectrum of injury severity. This suggests that the present training programme can be implemented in the treatment of all athletes. Furthermore, as it is reasonable to assume that ankle sprains not related to sports are comparable with those in sports, the programme could benefit the general population.

\textit{Implications for medical caregivers}

Medical caregivers rely heavily on evidence-based practice, using best research evidence available. The Cochrane Collaboration aims to improve healthcare decision making through systematic reviews of the effects of healthcare interventions, which can be seen as the highest level of evidence. A Cochrane review on interventions for preventing ankle ligament injuries found limited evidence for the reduction in ankle sprain recurrences after ankle disk training exercises.\textsuperscript{30} Since the publication of the Cochrane review, however, several randomised controlled trials on proprioceptive training, apart from our study, showed effectiveness in
preventing recurrences of ankle sprain. An updated Cochrane review could lead to new insights on how to treat ankle sprains, which could be useful for medical caregivers around the world.

What is already known on this topic
Ankle sprains are the most common injuries in various sports
Proprioceptive training reduces recurrences in ankle sprain recurrences by 50%
Despite treatment of an ankle sprain, risk of recurrence remains high

What this study adds
An unsupervised home based proprioceptive training programme prevents self reported ankle sprain recurrences in acutely injured athletes
Nine people need to be treated to prevent one recurrence
Proprioceptive training is a useful addition to usual care, specifically in athletes who did not have medical treatment for their ankle sprain

Contributors MDWH participated in formulating the study hypothesis, registered, analysed, and interpreted the data, discussed core ideas and participated in writing the paper. EALMV initiated and coordinated the formulation of the study hypothesis, registered, analysed, and interpreted the data, discussed core ideas and participated in writing the paper. WVM discussed core ideas, contributed to writing the paper, and is guarantor.

Competing interests None declared.

Funding This study is supported by a grant from the Netherlands Organization for Health Research and Development (ZonMw), grant number 750-20-002. No author or related institution has received any financial benefit from research in this study.

Ethical approval The study was approved by the Medical Ethics Committee of the VU University Medical Center, Amsterdam, the Netherlands. All athletes gave individual informed consent. Additional parent’s informed consent was given for athletes under the age of 18.
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Chapter 3
Effectiveness of the intervention

Appendix
Exercises of the eight-week proprioceptive training programme

One-legged stance
Stand on your right foot with relaxed, upright posture and with your left leg flexed at the knee; the left foot is off the floor.

Movement
Your right, weight-bearing leg should be lightly flexed at the knee, hip, and ankle, as if your right foot is on the ground during the act of running. Simply hold this position for one minute. Change to the left leg as the weight-bearing leg.

Number
Perform two sets of 15 reps for each leg.

Difficulty level
(1) perform the exercise on even surface
(2) perform the exercise on even surface with eyes closed
(3) perform the exercise on the balance board

Toe raise
Stand on both feet, upright with your heels over the edge of a raised surface. Make sure your feet are comfortably apart and your toes are pointing forward. Hold on to a wall or bar for balance.

Movement
Start with your heels down as far as possible in a good stretch. Keep your knees straight and stiff but not locked. Rise up onto the balls of your feet, moving only at the ankles. Your body should remain upright. Slowly lower your heels to the starting position in a controlled manner.

Number
Perform two sets of 15 reps for each leg.

Difficulty level
(1) perform the exercise on high surface with handhold
(2) perform the exercise on high surface without handhold
(3) perform the exercise on high surface with handhold

The edge of a raised surface. Make sure your feet are comfortably apart and your toes are pointing forward. Hold on to a wall or bar for balance.

Movement
Start with your heels down as far as possible in a good stretch. Keep your knees straight and stiff but not locked. Rise up onto the balls of your feet, moving only at the ankles. Your body should remain upright. Slowly lower your heels to the starting position in a controlled manner.

Number
Perform two sets of 15 reps for each leg.

Difficulty level
(1) perform the exercise on even surface
(2) perform the exercise on even surface with eyes closed
(3) perform the exercise on the balance board

The edge of a raised surface. Make sure your feet are comfortably apart and your toes are pointing forward. Hold on to a wall or bar for balance.

Movement
Start with your heels down as far as possible in a good stretch. Keep your knees straight and stiff but not locked. Rise up onto the balls of your feet, moving only at the ankles. Your body should remain upright. Slowly lower your heels to the starting position in a controlled manner.

Number
Perform two sets of 15 reps for each leg.

Difficulty level
(1) perform the exercise on even surface
(2) perform the exercise on even surface with eyes closed
(3) perform the exercise on the balance board
Preventing ankle sprain recurrences in sports athletes back in balance?

One-legged knee flexion Stand with your right foot forward and swing your left foot back, with your feet roughly one shin-length apart. Full bodyweight should be directed through the mid-foot region of your right foot.

Movement Bend your right leg at the knee and lower your body until your right knee reaches an angle of about 110° between the thigh and the lower leg. Keep the knee centred over the ball of the foot. As you carry out this squat your left arm should swing forward. Then return to the starting position, maintaining upright posture and returning your left arm to your side.

Number Perform two sets of 15 reps for each leg.

Difficulty level
(1) perform the exercise on even surface
(2) perform the exercise on even surface with eyes closed
(3) perform the exercise on the balance board

Toe walk Stand high up on your toes.

Movement Walk for 4 metres high up on your toes with your toes pointing forward, turn around and walk for 4 metres high up on your toes with your toes pointing outward. Turn around again and walk for 4 metres with your toes pointing in. When you point your toes out or in, be sure to turn your legs outward or inward from the hips.

Number Repeat the forward, toes-out, and toes-in pattern of toe walking 3 times for each leg.

Difficulty level
(1) walk on even surface
(2) jump on even surface
Crossed leg-sway Stand forward slightly with your hands on a wall or other support and your weight on your right leg.

Movement Swing your left leg to the right in front of your body, pointing your toes upwards as your foot reaches its farthest point of motion. Then swing the left leg back to the left as far as comfortably possible, again pointing your toes up as your foot reaches its final point of movement.

Number Repeat this overall motion 15 times with erect body posture and good balance.

Difficulty level
1. perform the exercise on even surface
2. perform the exercise on even surface with eyes closed
3. perform the exercise on the balance board

Runners’ pose Stand relaxed with erect body posture, with your feet five centimetres apart.

Movement Swing your left thigh ahead and upward until it is parallel to the floor (your leg should be flexed at the knee as you do this, so that the lower part of the leg is nearly perpendicular with the ground); simultaneously bring your right arm forward, as during a normal running stride. Hold this position for eight seconds and, while maintaining stability and balance, bring your left foot back to the ground and your right arm back to a relaxed position at your side.

Number Perform 15 repetitions for each leg.

Difficulty level
1. perform the exercise on even surface
2. perform the exercise on even surface with eyes closed
3. perform the exercise on the balance board
4. perform the exercise on even surface with handhold
