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The GronoRun study. Incidence, risk factors, and prevention of injuries in novice and recreational runners

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The ***GronoRun*** study

Incidence, risk factors, and prevention of injuries
in novice and recreational runners



Ida Buist

The GronoRun study

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in novice and recreational runners

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The GronoRun study

Incidence, risk factors, and prevention of injuries
in novice and recreational runners

1. Mannen lopen groter risico om een hardlooplessure te krijgen dan vrouwen. (dit proefschrift)
2. Alle hardlooplessures zijn te voorkomen. De grote vraag is hoe. (dit proefschrift)
3. Het toepassen van de 10% regel heeft geen preventief effect op de incidentie van hardlooplessures. (dit proefschrift)
4. Voor recreatieve lopers is het doen van een mentale warming-up zinvoller dan het uitvoeren van een fysieke warming-up.
5. De voornaamste reden om met hardlopen te beginnen is het bevorderen van de fitheid. (dit proefschrift)
6. Ruim 1 op de 4 recreatieve hardlopers raakt geblesseerd tijdens de voorbereiding op de 4 Mijl van Groningen. (dit proefschrift)
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in novice and recreational runners

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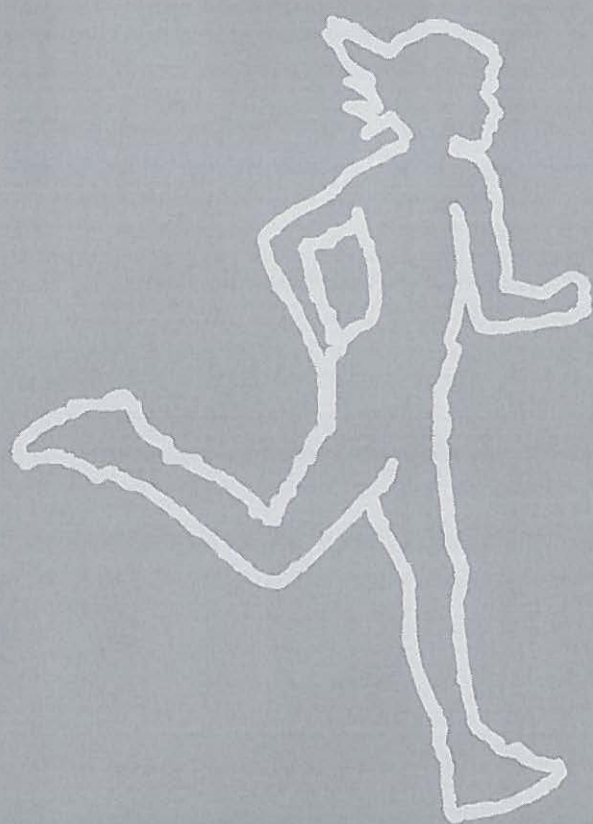
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Chapter 1

General Introduction

Running for health

Physical exercise is widely accepted as a key factor in promoting good health. It reduces the risk of developing non-insulin-dependent diabetes mellitus, latent autoimmune diabetes, and coronary heart disease.¹ Fitness and health are becoming important aspects of the modern lifestyle. As of 2000, the percentage of people in the Netherlands that is engaging in vigorous exercise for 20 minutes at least three times per week has steadily increased from 19% to 24%.² Among these activities, running was already a popular form of exercise in the late 1970s. A newly-found interest in recreational running can be observed nowadays.³ More people, especially women, include running as part of their healthy active lifestyle. Running has changed from being mainly a competitive sport to also being a popular leisure-time activity.⁴

Although running is a form of recreational exercise that is beneficial for fitness and health, injuries are a significant side effect. Reported rates of running-related injuries are high, and vary from 30 to 79%.⁵⁻¹¹ To keep the running population active without injuries leading to periods of forced inactivity there is a need for preventive interventions. Many different methods to prevent injuries are currently being recommended and practiced by runners. However, to date no preventive interventions have been tested in the population of recreational and novice runners for their preventive capabilities.

Understanding causes and risks are essential for establishing preventive interventions. Research on injury prevention in sports typically follows a sequence described by van Mechelen et al.¹² Firstly, the extent of the problem must be identified and described in terms of the incidence and severity of sports injuries. Secondly, the risk factors and injury mechanisms that play a part in causing sports injuries must be identified. The third step is to introduce measures that are likely to reduce the future risk of sports injuries. Such measures should be based on information about the etiological factors and the injury mechanisms as identified in the second step. Finally, the effect of the measures must be evaluated.

The literature on the aetiology of injuries in novice runners is scarce. Up until now, only three prospective cohort studies on the topic of incidence and risk factors of injuries in novice and recreational runners can be found.^{5,6,10} In the literature, several modifiable risk factors are suggested with the potential to



prevent running-related injuries.¹³ These suggestions for injury prevention have focused on the use of protective devices such as braces and insoles¹⁴⁻¹⁹, stretching exercises^{14,20,21}, and modifying training schedules^{14,22,23}. Traditions of modifying a training schedule are to alter the training frequency or duration. Although there are no studies that quantify optimal training loads, an increase of no more than 10% per week is suggested to prevent the occurrence of a running-related injury.²⁴ This guideline is known as the '10 Percent Rule'. Nevertheless, there is no evidence to prove that modification of a training program by applying the 10 Percent Rule has an effect on the number of injuries among runners.

Outline of the thesis

The present thesis describes the Groningen Novice Running (Gronorun) project, which was designed to study the incidence, risk factors and prevention of running-related injuries in novice runners. The main purpose of this thesis is to determine the effect of a modified (i.e. graded) training program for novice runners, based on the 10 Percent Rule on the incidence of running-related injuries. The secondary purpose is get more insight into the incidence and risk factors for injury in recreational and novice runners. First, an overview is given of current concepts in running-related injuries in **Chapter 2**. Since there is only a limited number of epidemiological studies on running-related injuries in novice and recreational runners, a systematic review of the literature was not performed. Before the Gronorun study, a pilot study was conducted to gain more insight into incidence and risk factors for injuries in recreational runners. **Chapter 3** describes this pilot study, in which recreational runners were prospectively followed during an eight-week training period preparing for the 4-mijl van Groningen (Groningen 4-mile run) event. It was shown that among recreational runners, novice runners were the ones most susceptible to sustain a running-related injury. For that reason a preventive intervention – a graded training program applying the 10 Percent Rule – was developed to decrease the incidence of running-related injuries among novice runners. The design of the randomised controlled trial (i.e. the Gronorun study) testing the effect of this intervention is presented in **Chapter 4**. **Chapter 5** presents the main outcome of this Gronorun study, that is, the effectiveness of a graded training program on the number of running-related injuries among novice runners.

Chapter 6 reports on the predictors of running-related injuries among male and female novice runners following a beginners' training program. **Chapter 7** contains the general discussion, summarising the main conclusions, followed by a reflection on the methodological considerations concerning the results of this thesis. Finally, recommendations for practice and future research are described.



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Chapter 2

Aetiology of Injuries in Recreational Runners

Current Concepts

Buist I & Bredeweg SW

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Abstract

Recreational running is a popular sport. As the numbers of participants increase, so do the number of running-related injuries. The incidence of injuries among runners is high and varies between 2.5 and 38 per 1000 hours of running. The diversity of incidence strongly depends on study population, definition and assessment of injury, and period of follow-up. Although there is much literature concerning running-related injuries, there is little agreement when it comes to the aetiology of these injuries. Risk factors that are consistently associated with the occurrence of injuries in runners are higher running mileage and previous injury. There is a lack of proof for the link between gender, age, anatomical variation and biomechanical variables, psychological factors and running-related injuries.

Introduction

An increasing number of people realises that physical exercise is beneficial for their health. Running is one of the most accessible recreational sports. It can be done at any time and anywhere, and one does not need special equipment besides a pair of running shoes and comfortable clothes. This motivates many people to start running each year. In the Netherlands around 800,000 people are engaged in regular running, and there are over two million occasional runners. Running is one of the most popular forms of recreational exercise. Not only in the Netherlands, but also worldwide the number of runners as well as the number of running events are growing. Almost every city has its own annual running event in which runners of all levels participate. Although running is a form of recreational exercise that has a positive effect on fitness and health, it also has a high incidence of injuries.

The literature on injuries in novice runners is scarce. Only a limited number of prospective cohort studies on the topic of incidence and risk factors of injuries in novice and recreational runners can be found.¹⁻³ Bovens et al.¹ studied 115 volunteers during a training program. The participants who had limited or no running experience were asked to keep a diary in which they registered information on the training program and injuries. The primary outcome in this study was the incidence of running related injuries. Nevertheless, there was no assessment of potential risk factors. Lun et al.² assessed both potential risk factors for RRI at baseline as well as the exposure time and injury data during the follow-



up. However, participants were already running more than 20 km per week at baseline. In the study by Taunton et al.³ several running training clinics were investigated to determine the number of injuries that occur in a running programme designed to minimise the injury rate for athletes training for a 10 km race. The relative contributions of factors associated with injury were also reported. Instead of using a baseline questionnaire, the potential risk factors were assessed by means of a questionnaire that was administered on three separate trials over the 13-week training period. Also, the results did not take into account an adequate measure of exposure time to injury.

The purpose of this chapter is to outline the current concepts regarding the incidence and risk factors of running related injuries. It also highlights some methodological issues of particular importance when reading the literature on the aetiology of injuries among runners. A thorough review of the aetiology of running related injuries in general is beyond the scope of this discussion. Excellent reviews of this information are available in previous publications.^{4,7}

Overuse injuries

Although acute injuries in runners do occur (i.e. ankle sprain or traffic injury), most runners' injuries are overuse injuries.⁸ Each kilometre an average runner's foot lands 800 times, with forces that are as high as two to three times the runner's body weight.⁹ Per definition, injuries occur when energy is transferred to the body in amounts or at rates that exceed the threshold for human tissue damage. An overuse injury is an injury of the musculoskeletal system resulting from the combined fatigue effect of multiple loads over a period of time. In running, an overuse injury is the result of a large number of small-magnitude repetitive forces, each lower than the acute injury threshold of the structure.

In overuse injuries, the cumulative load applied on the musculoskeletal system is higher than the injury threshold of a specific structure of the musculoskeletal system. When this structure is injured due to overuse, it means its capacity was insufficient in proportion to the applied stresses.⁸ If the applied training load is sufficient and the time between two training sessions lasts long enough, there will be a positive adaptation of the musculoskeletal system. The muscles, bones and connective tissues that were stressed will become stronger.

Since running mainly loads the lower extremities, most running-related injuries, i.e. 69 to 91%, are located at the knee and below.^{1,3,10,11} The most common injuries in runners are patellofemoral pain syndrome, iliotibial band friction syndrome, plantar fasciitis, and achilles tendinopathy.¹²

Incidence of running-related injuries

There are different ways to specify the incidence of sports injuries. The most common ways of reporting running-related injuries are absolute number of injuries, proportions of injuries, and number of injuries per exposure. The incidence of running-related injuries is preferably expressed in the number of injuries per 1000 hours of running. Van Mechelen⁷ showed in his review an incidence of 2.5 up to 12.1 injuries per 1000 hours of running. Lun et al.² found in their study an incidence of 59 per 1000 hours of running exposure. Results that have been presented as proportions or numbers of injuries are of limited value, because they do not take different levels of exposure to risk factors into account.¹³

Expressing the incidence in the number of injuries per 1000 hours of running also simplifies comparison of results between different studies. Other ways to present the relative number of running-related injuries are the number of injuries per 100 runners at risk, or the percentage of injured runners. These methods of reporting incidence of injuries are most frequently seen because the information on exposure time is not always available. In a prospective cohort study of 1680 runners participating in two running events, 48% experienced at least one injury during a 12-month follow-up.¹⁰ Among participants of a popular 16-km race, 46% of the male participants sustained running injuries during the one-year study period.¹⁴ Macera et al.¹⁵ found in their prospective study of 538 habitual runners that 51% experienced an injury. In another prospective cohort study, 255 runners preparing for a marathon were followed. During the 32-week follow-up, 35% sustained an injury.¹⁶ Lun et al.² found that during a follow-up of six months, 79% of 87 recreational runners experienced at least one injury of the lower extremity. A recently published review of lower extremity injuries in long-distance runners showed rates varying from 19.4 to 92%.⁶ The reported incidence numbers strongly diverge. The wide range of incidence rates that have been reported in the literature is caused by differences in study populations, follow-up periods, and definitions of injury.



Definition of injury

The definition of a running-related injury differs between studies. The definition of an injury in epidemiological studies on running-related injuries is frequently stated as: i) ailment or pain;^{1,3,10,11,15,17,18} ii) caused by running;^{1,15,17} iii) resulting in a restriction of running;^{1,2,10,11,15,17,18} iv) for at least one week.^{17,18} In one single study, pain without a restriction of running was considered as an injury.³ It is understandable that the incidence will be higher as the definition of injury becomes broader. Participants' level and assessment of injury will also influence the incidence. Elite runners will have different training routines and will therefore be more exposed to running than novice runners.

Aetiology of running-related injuries

Factors that may influence the aetiology of running-related injuries can be classified in several ways. Most studies are about overall injuries in runners, instead of a specific diagnosis or anatomical site. They are frequently classified as intrinsic (personal related) and extrinsic (training related) risk factors. Personal related risk factors can also be subdivided into anthropometric, anatomical, biomechanical and psychological variables, and previous injury.

The training-related variable that is most frequently associated with the occurrence of a running-related injury is excessive running distances.^{10,14,15} A higher weekly running distance leads to more time at risk and is therefore associated with more injuries. A sudden increase of running distance or running pace is also a risk factor for injuries in runners.^{11,15} An increase of no more than 10% per week is regarded as safe in the literature in order to prevent injuries.¹⁹ Other training-related variables linked to the occurrence of a running-related injury are running frequency,^{3,10,15} implementation of stretching exercises,^{10,15} footwear^{3,11} and running surface.^{15,20}

Running surface and footwear

In the Netherlands as well as worldwide, most people run on a hard surface such as asphalt or concrete. The advantage is that this surface is flat, therefore the risk of

sustaining an ankle sprain or another acute injury will be low. On the other hand, hard surfaces may place higher levels of stress upon the structures of the musculoskeletal system. In the non-scientific literature the emphasis lies on wearing proper shoes to prevent injuries in runners. It is frequently written that novice runners are advised to visit a specialist in order to select proper running shoes. However, the terms 'specialist' and 'proper running shoes' are difficult to operationalise. Older shoes are said to lose their shock-absorbing functioning, probably leading to higher stresses on the musculoskeletal system. A recently published study showed that three brands of low- and medium-priced running shoes tested provided the same (if not better) cushioning of plantar pressure as high-cost running shoes.²¹

Anthropometric variables

Several characteristics of a runner i.e. gender, age, Body Mass Index (BMI) and previous injury, are associated with injury. The results from a recent systematic review article on risk factors for RRI in long-distance runners showed a positive link with the female gender.⁶ The link between age and the occurrence of running-related injuries seems controversial. In the 1980s study participants were primarily male runners, and in those studies no significant association was found with age.^{10,15} More recently, a prospective cohort study showed that females older than 50 were two times more at risk than younger female participants.³ It is plausible that due to the aging process the structures of the musculoskeletal system become more prone to injury. On the other hand, as runners become older they may also be more familiar with early signs of a running-related injury, and perhaps only the injury-free runners will continue to run. Marti et al.¹⁴ calls this the 'healthy runner effect'.

The association between BMI and injury has been studied several times, but findings are not consistent. One study showed that male runners with a BMI higher than 26 had fewer injuries compared to male runners with a BMI of 26 or less.³ In this study the potential risk factors were not corrected for running exposure. Therefore, running exposure could be a confounding factor, that is, heavier persons may have been less exposed to running. Another study showed that participants with a BMI lower than 19.5 or higher than 27 had an increased risk of sustaining a running-related injury.¹⁴



Anatomical variables

A number of anatomical variables is associated with running-related injuries. Of the various lower extremity 'misalignments', high longitudinal arch (pes cavus) and low longitudinal arch (pes planus) are probably the factors most commonly associated with running-related injuries.⁸ A high longitudinal arch is frequently said to be associated with a stiff foot, resulting in a reduced capability of shock absorption. Although a pes cavus or a pes planus could be associated with a higher risk of injury, this is not consistently shown in research.⁸ Wen et al.¹⁶ found in runners with both high and low longitudinal arches an increased risk for sustaining an injury. However, Lun et al.² found no obvious predominance of subtalar valgus or pes planus/cavus in those who were injured. In another prospective study the knee (valgus/varus), the longitudinal arch and the score of the rearfoot (valgus/varus) were measured. None of these anatomical variables appeared to have an association with the occurrence of a running-related injury.¹⁰

Other anatomical variables that may be linked to injuries in runners are the range of motion (ROM) of the hip and ankle.^{2,5,22,23} Whether these variables are risk factors for the occurrence of running-related injuries has yet to be determined.

Biomechanical variables

The majority of the biomechanical factors that are associated with injuries in runners can be classified as kinetic or rearfoot kinematic variables. Kinetic variables that have been associated with running-related injuries are the magnitude of impact forces, the rate of impact loading, the magnitude of active forces, and the magnitude of joint moments.^{8,24} Pronation of the foot is the rearfoot kinematic variable that has been suggested to be most often related with an injury in runners.⁸ Pronation is a protective mechanism during running which absorbs shocks by dividing forces over a longer period of time. In situations of abnormal pronation, that is pronation beyond midstance, potentially large torques and instability are generated. On the basis of information provided by static tests it is frequently stated that injured runners have excessive pronation. In the study of Messier and Pitalla²² it was shown that injured runners had more pronation and higher pronation velocity than non-injured runners. In a more recent study it was

suggested that runners who had developed stride patterns that incorporated a moderately rapid rate of pronation were at a reduced risk of incurring overuse running injuries.²⁵

Navicular drop is used to clinically measure dynamic foot pronation,²⁶ and is defined as the change in height of the navicular bone when the foot moves from a subtalar neutral to a relaxed weightbearing stance.²⁷ Reinking and Hayes²⁸ showed that athletes with an exercise-related lower leg pain history did not have a greater foot pronation as measured by navicular drop compared to those without previous injury.

Previous injury

History of previous injury is the strongest intrinsic risk factor of injuries in runners. An injury in the twelve months prior to the study is frequently labelled as a previous injury.⁷ Both among female and male runners, a previous injury is shown to be a risk factor for subsequent injury.¹⁵ Walter et al.¹⁰ showed that runners with a previous injury had approximately a 50% higher risk for a new injury during the follow-up. Reasons for this phenomenon may be that the causal factor is still present, or that the previous injury did not heal completely.

Psychological variables

Whereas some runners hardly ever sustain injuries, others have recurrent running-related injuries. Ekenman et al.²⁹ compared selected personality traits in a group of runners who had sustained a previous tibial stress fracture with a matched group of runners who had never experienced stress fractures. The results indicated that the injured runners, especially the women, scored higher than the non-injured runners on inventories measuring both type-A behavioural pattern and exercise dependency. People who run to compete instead of running to increase their level of fitness are said to be more prone to injury.⁷ Runners with increased levels of motivation are more likely to be injured. Several authors allude to the existence of a certain 'readiness to take risks' among athletes who became injured.³⁰ The hypothesis is that strongly motivated runners will ignore the first signs of an injury and will hold on to their training program.



Conclusion

The incidence of running-related injuries is substantially high. Although there is a large body of literature on the subject of risk factors for running-related injuries, there is little consistency on the reporting of incidence, the aetiology and the risk factors of these injuries. The two most important factors for the occurrence of injuries in runners are higher running mileage and previous injury.

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Chapter 3

Incidence and risk factors of Running-Related Injuries during preparation for a four-mile recreational running event

A prospective cohort study

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Abstract

Objective: To determine the incidence and to identify gender-specific predictors of Running-Related Injury (RRI) among a group of recreational runners training for a four-mile running event.

Design: Prospective cohort study.

Methods: Several potential risk factors were prospectively measured in 629 novice and recreational runners. They were observed during an eight-week training period for any running-related musculoskeletal injuries of the lower limbs and back. A running-related injury was defined as any musculoskeletal pain of the lower limb or back causing a restriction of running for at least one day.

Results: At least one RRI was reported by 25.9% of the runners during the eight-week observation period. The incidence of RRI was 30.1 (95% confidence interval (CI) 25.4–34.7) per 1,000 hours of running exposure. Multivariate Cox regression showed that male participants were more prone to sustain a running-related injury than female participants (HR 1.4; 95% CI 1.0–2.0). No prior running experience was the most important risk factor in male (HR 2.6; 95% CI 1.2–5.5) and female (HR 2.1; 95% CI 1.2–3.7) participants.

Conclusions: The incidence of running-related injuries in recreational runners preparing for a four-mile running event is substantially high. Male and female participants have different risk profiles. Furthermore, the findings suggest that novice runners are the most availed by preventive interventions for RRI.



Introduction

The popularity of running as a recreational activity is high and is still increasing. Nowadays, almost every city in Western society has its own marathon and recreational running events. The reason for novice runners to participate in a running program is most likely to improve health and fitness, and for intermediate runners to improve personal performance.¹

Besides its beneficial health effects, running also puts runners at a risk of developing a Running Related Injury (RRI). In the literature, injury rate of RRI is expressed in number of RRIs (or injured runners) per 100 runners at risk, and when exposure is measured, also the incidence of RRI in number of RRIs (or injured runners) per 1,000 hours of running.² Reported injury rates of RRIs per 100 runners at risk is high, and varies from 30 to 79%,^{1,3,8} and injury incidence from 7 to 59 RRIs per 1,000 hours of running.^{3-5,9} The wide disparity of incidence rates found in several studies on RRI is caused by variations in definition of injury, differences in population at risk (novice, recreational and elite runners with different training loads), and differences in the duration of follow-up periods (time at risk). Most of the RRIs (50-75%) are overuse injuries located at the knee or below.¹⁰⁻¹⁷

The aetiology of the RRIs is multifactorial, with both intrinsic (personal) and extrinsic (environmental) factors contributing. Intrinsic factors include age, gender, BMI (Body Mass Index), physical fitness, previous injury and anatomical alignment. Extrinsic factors can be running distance and frequency per week, predominant running surface, running shoe age and running shoe type. In the literature, only four factors (reported running experience, previous injury, running to compete and excessive weekly running distance) have been associated consistently with RRI.² A more recent systematic review on determinants of lower extremity running injuries in long-distance runners shows that higher training distance per week in male runners and a history of previous injuries in male and female runners were risk factors for sustaining an RRI.¹⁸ Conflicting or no evidence is found for other factors like age, BMI, static biomechanical alignment, running surface, running frequency, warm-up and stretching.¹⁸ Furthermore, male and female runners have different risk profiles for RRI.¹ In addition, risk factors can interact, and therefore should be considered simultaneously to adjust for

confounding.¹⁹ Eventually, a combination of intrinsic and extrinsic risk factors predisposes runners to develop an RRI.

Until now, most of the studies on incidence and risk factors of RRI are conducted on long-distance runners. Inclusion of novice runners in prospective cohort studies on the risk factors for RRI will reduce the healthy runner selection bias.²⁰ Only a limited number of studies exist that control for the time at risk, i.e. exposure time, and little is known about different risk profiles for RRI between male and female recreational runners. Therefore, the purpose of this study is to determine the incidence of RRI and to identify gender-specific predictors of RRI among a group of novice and recreational runners training during an eight-week period for a four-mile running event.

Methods

Study period and settings

A prospective cohort design was used for the study. A flowchart of the study is shown in figure 3.1. Potential participants for the study were 1459 recreational runners who signed up for the 'four-mile training program', an eight-week program to prepare for the Groningen four-mile. The Groningen four-mile is a major recreational annual running event in the northern part of the Netherlands. Over 15,000 mainly novice and recreational runners participate in it each year in the first week of October.

Study procedure and subjects

All participants (n=1459) who signed up for the four-mile training program were invited by mail to participate in the study. Along with the invitation, information about the study, a baseline questionnaire, an informed consent form, and a running diary were sent. The only exclusion criterion was being under 18 years of age. The standardised baseline questionnaire covered demographic variables and questions on potential risk factors for RRI.

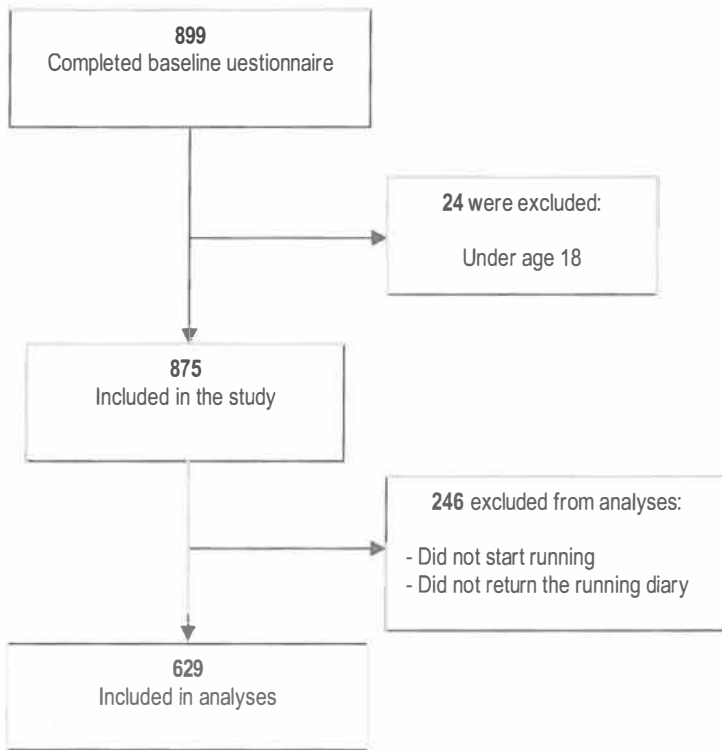


Figure 3.1: flow chart of the Groningen four-mile study

The potential risk factors for RRI that were assessed by the baseline questionnaire were age, gender, BMI, current and past musculoskeletal injuries of the lower limb, running experience and current running routines (years of experience and frequency and duration in hours per week), participation in other sports (hours per week and type of sports: axial loading or non-axial loading) and motivation for entering the program (health/fitness or competitive/personal performance). Running experience was assessed by the baseline questionnaire. The participants had to categorise themselves as novice runners, runners with previous experience who have taken up running again, or runners who were already engaged in regular running.

During the program, participants registered information on exposure to running and RRI in a personal running diary. The running diary consisted of eight sections (one for each training week). The total minutes of running and the occurrence of running-related pain during or after running was registered per day. The running-related pain was scored as pain after running, pain during running without a restriction of running, pain that caused a restriction of running mileage, -pace, or -duration, or running not possible as a result of running-related pain. At the end of the program the participants returned their running diary by mail.

The study design, procedures and informed consent procedure were approved by the Medical Ethics Committee of University Medical Center Groningen (UMCG). All participants provided written informed consent.

Training program

The training program was developed by a coach of the Royal Dutch Athletics Association. Five training clinics were part of the training program and were organised by local running clubs at the end of the third to seventh weeks. The eight-week training program required participants to run three times per week in the first to seventh weeks and twice in the last week of the program. The program finished with the four-mile running event at the end of the eighth week. Within the training program for the Groningen four-mile, deviations were made for novice and recreational runners. The training program for novice runners started with ten one-minute repetitions of running alternated by one minute of walking. The training program for experienced runners started with 30 minutes of continuous running. The exposure time of running in the training programs for novice and



recreational runners varied respectively between 10 to 40 minutes and 20 to 60 minutes per training.

Injury definition

A running-related injury was defined as any musculoskeletal pain of the lower limb or back causing a restriction of running (mileage, pace, or duration) for at least one day.

Analyses

Demographic variables and potential risk factors for RRI were analysed for differences between male and female participants at baseline using two-tailed t-tests for normally distributed continuous variables. Chi-square statistics were used for discrete variables. Differences were considered statistically significant at $p < 0.05$. Incidence of RRI was calculated for all participants and for male and female separately as the number of new injuries reported per 1,000 hours of running exposure. Exposure time (in hours of running exposure) was calculated from the time a participant started the running program until he reported an RRI (injured runners) or until the end of the program (non-injured runners).

Potential risk factors for RRI were first univariately analysed to see the independent relation with RRI. Variables independently associated ($p \leq 0.25$) with RRI among either male or female were entered in gender-specific multivariate Cox regression prediction models. Hazard Ratios (HR) and the corresponding 95% CI were calculated for the factors associated with RRI. All analyses were performed using SPSS version 14.0 (SPSS Inc, Chicago).

Results

A total of 1459 recreational runners signed up for the four-mile running clinics. Among them, 899 were willing to participate in the study and completed the baseline questionnaire.

Of the 899 who consented to participate, 24 were under age 18 and were therefore excluded. Data of 629 out of 875 participants were analysed, 207 male (33%) and 422 female (67%). Two hundred forty-six participants neither started running nor returned their running diary over the full eight-week period. Consequently, they were excluded from data analyses.

Table 3.1: Baseline characteristics

	All (n=629)	Male (n=207)	Female (n=422)
Age (years)*	43.7 (9.5)	46.5 (9.4)	42.3 (9.2)
BMI (kg/m²)*	24.9 (3.3)	25.9 (3.2)	24.4 (3.2)
Motivation			
<i>Health-oriented</i>	439 (69.8%)	144 (69.6%)	295 (69.9%)
<i>Personal performance</i>	190 (30.2%)	63 (30.4%)	127 (30.1%)
Not previously active*	280 (44.5%)	118 (57.0%)	162 (38.4%)
Previously active*	349 (55.5%)	89 (43.0%)	260 (61.6%)
<i>hours/week (n=349)</i>	2.4 (1.7)	2.7 (1.8)	2.3 (1.7)
No prior running experience	199 (31.6%)	56 (27.1%)	143 (33.9%)
Restarting running	275 (43.7%)	100 (48.3%)	175 (41.5%)
Already participating in running	155 (24.6%)	51 (24.6%)	104 (24.6%)
<i>Previous weekly running frequency (n=155)</i>	2.3 (0.7)	2.4 (0.9)	2.2 (0.6)
<i>Previous running hours per week (n=155)</i>	1.2 (0.8)	1.5 (1.0)	1.1 (0.7)
Previous injury of lower extremity			
<i>No previous injury</i>	230 (36.6%)	66 (31.9%)	164 (38.9%)
<i>< 1 year</i>	186 (29.6%)	55 (26.6%)	131 (31.0%)
<i>≥ 1 year</i>	213 (33.9%)	86 (41.5%)	127 (30.1%)

Values are numbers with standard deviations or percentages in parentheses.

* Significance difference between male and female $p < 0.05$.

BMI, Body mass index.



Baseline characteristics

Baseline characteristics of 629 recreational runners are shown in Table 3.1. Most of the participants used the training program to restart running (44%) or were already participating in running (25%). The main reason for participating in the training program was to improve fitness and health (70%). Male participants (33%) were 4.2 years older ($p < .05$) than female participants (67%), and showed a significantly higher BMI (25.9 versus 24.4, $p < .05$). Furthermore, male participants were less active in sports (43% versus 62% in female participants) prior to the training program ($p < .05$).

Running diary analysis

Exposure of running

Over the eight-week period of the program, mean exposure time of running among female participants was 9.1 hours (sd 5.5) versus 9.8 hours (sd 5.3) for male participants. The novice runners ran 7.1 hours (sd 5.9), while the experienced runners had an exposure time of 13.1 hours (sd 5.4) in the eight-week training period. The increase of weekly exposure is illustrated in Figures 3.2a-c.

Incidence of RRI

A total of 163 new RRIs were recorded by 629 runners at risk. To estimate the incidence, i.e. the number of RRIs per 1,000 hours of running exposure, exposure time until the first RRI was used. Therefore, the exposure time in Table 3.2 is somewhat lower than the total exposure time. The incidence of RRIs per 1,000 hours of running exposure was 30.1 (95% CI 25.4–34.7). The difference between the incidence of RRIs per 1,000 hours of exposure in male and female participants was 7.5 (95% CI -2.6–17.6). The injury rate, i.e. the number of RRIs per 100 runners at risk, was significantly higher in male participants than in female participants (31.4% versus 23.2%, $p = .03$). If pain as a result of running (without restriction of running) was included in the definition of RRI, the number of RRIs per 100 runners at risk would be as high as 59.9% in male and 60.6% in female participants.

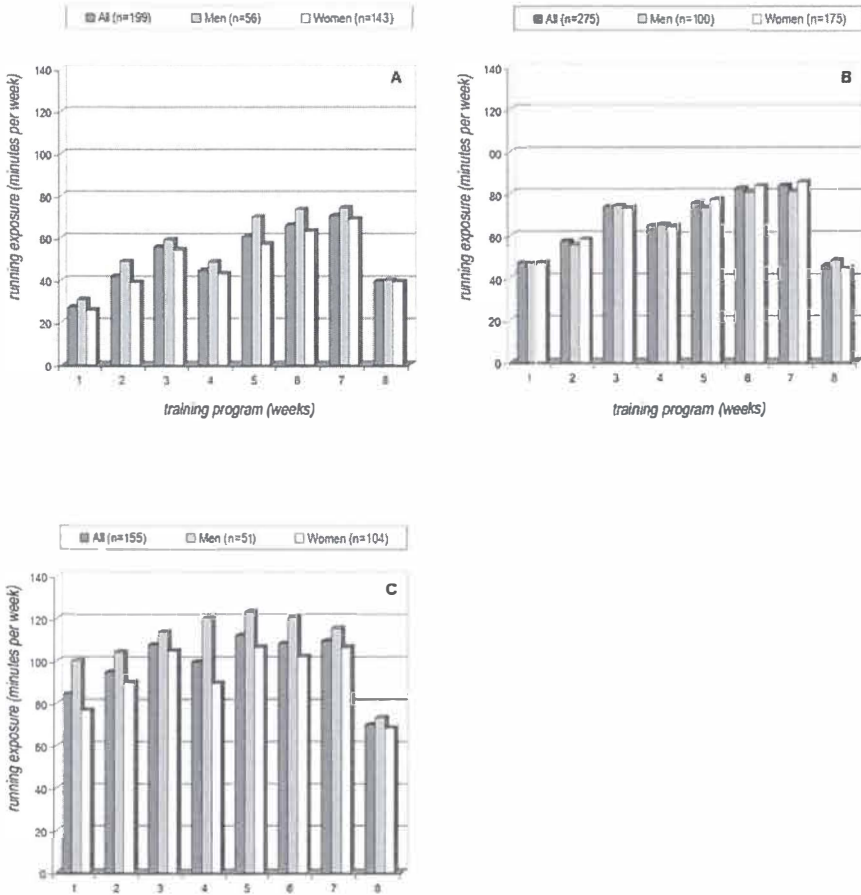


Figure 3.2: mean exposure time per week for A) novice runners, B) runners with previous experience who have taken up running again, and C) runners who were already engaged in regularly running.

Of all runners sustaining an RRI, 39 out of 98 (40%) female runners and 24 out of 65 (37%) male runners did not restart running during the eight-week training period ($p > .05$). Among novice runners, significantly more ($p = .02$), i.e. 30 out of 62 (48%) did not restart running after sustaining an RRI, compared to eight out of 33 (24%) among runners who were already engaged in regularly running at baseline. Among the runners with previous running experience who had taken up running again, 25 out of 68 (37%) did not restart running.



Table 3.2: Number and percentage of participants sustaining RRP and RRIs, total running exposure time, and incidence of RRI per 1,000 hours of running exposure during the eight-week follow-up

	No pain	RRP	RRI	Exposure (hours)	Incidence (n/1,000h)	95% CI
Female (n=422)	166 (39.3%)	158 (37.4%)	98 (23.2%)	3565.4	27.5	(22.0-32.9)
Male (n=207)	83 (40.1%)	59 (28.5%)	65 (31.4%)	1857.2	35.0	(26.5-43.5)
Total (n=629)	249 (39.6%)	217 (34.5%)	163 (25.9%)	5422.6	30.1	(25.4-34.7)

RRP = Running-related pain without restriction of running
RRI = Running-related injury causing a restriction of running for at least one day.

The anatomical distribution of all RRIs is shown in Figure 3.3. The lower leg (calf and shin) was the most frequently injured anatomical site in females (35 out of 98), and the knee in male participants (25 out of 65). Most of the RRIs appeared at the knee and below in female (67%) and in male participants (80%). The only significant difference between male and female participants was the percentage of RRIs localised at the knee, that is, 23% in female versus 39% in male participants.

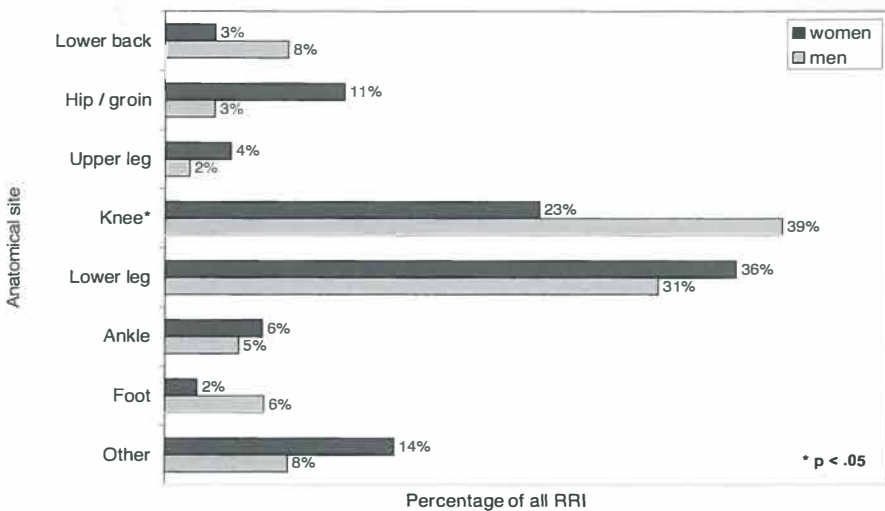


Figure 3.3: Anatomical distribution of RRIs in male and female participants

Risk factors for RRI

All variables assessed at baseline were analysed to see the relation with the occurrence of an RRI. An overview of all potential risk factors and hazard ratios is shown in Table 3.3.

Table 3.3: Univariate Cox regression models for male and female participants

	Male (n=207)			Female (n=422)		
	HR	95% CI	p	HR	95% CI	p
Gender	1.3	.96 – 1.80	.09	1.0		
Age, per 10 years	.69	.53 – .90	.01 *	.98	.96 – 1.01	.15
BMI, per kg/m²	1.03	.95 – 1.11	.47	1.08	1.02 – 1.14	.01 *
Motivation						
<i>Competition</i>	1.0			1.0		
<i>Health-oriented</i>	1.49	.84 – 2.66	.17	1.08	.70 – 1.67	.73
Previous sports activity						
<i>Previously active (axial load)</i>	1.0			1.0		
<i>Previously active (non-axial load)</i>	.95	.44 – 2.05	.90	1.84	1.06 – 3.19	.03 *
<i>Not previously active</i>	1.14	.61 – 2.14	.68	1.64	.95 – 2.83	.08
Running experience						
<i>No prior running experience</i>	2.20	1.06 – 4.58	.04 *	2.32	1.34 – 4.02	.00 *
<i>Restarting running</i>	1.95	1.00 – 3.81	.05 *	1.31	.75 – 2.28	.35
<i>Already participating in running</i>	1.0			1.0		
Previous weekly running frequency (n=155)	1.08	.59 – 1.97	.81	1.92	.94 – 3.93	.08
Previous running hours per week (n=155)	1.00	.99 – 1.01	.65	1.00	.99 – 1.01	.38

Univariate Cox regression analyses

The univariate Cox regression analyses showed that male participants were not at higher risk than female participants (HR 1.3; 95% CI 1.0–1.8). The variable age was significantly related with sustaining an RRI in male participants – that is, younger male runners were at higher risk of sustaining an RRI ($p < .001$). Furthermore, running experience was protective for sustaining an RRI. BMI, motivation for entering the program, previous sports activity and previous injury of the lower extremity were not significantly associated with RRI ($p > .05$).



Higher BMI in female participants was related to the risk of sustaining an RRI ($p < .05$). Univariate Cox regression analysis also shows that in female participants (non-axial) previous sports activity (HR 1.8; 95% CI 1.1–3.2), and no previous running experience (HR 2.3; 95% CI 1.3–4.0) were significantly associated with the hazard of sustaining an RRI. All other variables assessed at baseline were independently not significantly associated with RRI (see Table 3.3).

Multivariate Cox regression analyses

Table 3.4 shows the significant factors of the multivariate Cox regression models for male and female participants separately. Gender (male), corrected for age, BMI, previous sports activities and running experience were significant related to RRI (HR 1.4; 95% CI 1.0–2.0). Older age was associated with lower risk of RRI in male participants. Lack of running experience was the most important risk factor for RRI in males (HR 2.6; 95% CI 1.2–5.5) and in females (HR 2.1; 95% CI 1.2–3.7). Furthermore, female runners who reported engaging in non-axial sports activities at baseline were at a higher risk (HR 1.9; 95% CI 1.1–3.2) of sustaining an RRI. Higher BMI was also a risk factor for RRI in female participants (HR 1.1; 95% CI 1.0–1.1).

Table 3.4: Multivariate Cox regression models for male and female participants

	Male (n=207)			Female (n=422)		
	HR	95% CI	p	HR	95% CI	p
Gender	1.42	1.02 – 1.99	.04 *	1.0		
Age, per 10 years	.63	.48 – .82	.00 *	.82	.66 – 1.02	.07
BMI, per kg/m²	1.02	.94 – 1.11	.58	1.06	1.01 – 1.13	.03 *
Previous sports activity						
<i>Previously active (axial load)</i>	1.0			1.0		
<i>Previously active (non-axial)</i>	.88	.41 – 1.93	.76	1.85	1.07 – 3.21	.03 *
<i>Not previously active</i>	1.08	.57 – 2.04	.81	1.53	.88 – 2.66	.13
Running experience						
<i>Already participating in running</i>	1.0			1.0		
<i>Restarting running</i>	2.24	1.13 – 4.45	.02 *	1.15	.65 – 2.02	.63
<i>No prior running experience</i>	2.61	1.23 – 5.53	.01 *	2.14	1.24 – 3.70	.01 *

Discussion

The aim of this prospective cohort study was to determine the incidence of RRI, expressed as the number of RRIs per 1,000 hours of running and per 100 runners at risk, and to determine the gender-specific risk factors associated with RRI in recreational runners who are training for a four-mile (6.7 km) recreational running event in an eight-week period. Information gathered by means of this study is used to determine who are at risk for developing an RRI.

Incidence and characteristics of RRI

The incidence of RRI of 25.9% in our cohort of 629 recreational runners at risk is comparable with the incidences found in other studies. The 'Vancouver Sun Run' study¹ showed an injury incidence of 29.5% in a group of runners following a 13-week training program preparing for a 10-km running event. A second study, also on recreational runners, showed an incidence of 58%³ with novice participants training for a 15-km run during a period of 28 weeks. Since our study had a shorter follow-up and therefore less time at risk, the smaller number of RRIs per 100 runners at risk may be obvious. If we defined RRI according to the definition of Taunton et al.¹ – pain as a result of running – the number of RRIs per 100 runners at risk would be as high as 60.4%.

Only a few studies on RRIs have assessed exposure time in a way that the incidence per 1,000 hours of exposure to running could be calculated. The overall incidence of 30/1,000 hours of running exposure was higher than the incidence of 12/1,000 hours found by Bovens et al.³ Although the definitions of RRI were identical, duration of follow-up and ultimate goal of training were different – training for a marathon versus a four-mile race. Lun et al.⁴ found an incidence rate of 59/1,000 hours of exposure during a follow-up of six months. The most important difference with this study is that participants were already running more than 20 km/week at baseline. Also, 46 participants were lost to follow-up whereas only 87 runners were included in the analyses. Our study showed that over 70% of the RRI were localised at the knee and below. This result is in line with other studies on RRI.^{1,3,7} Novice runners were the most disadvantaged by an RRI, that is, did not restart running after sustaining an RRI. This might not be such a strange finding. Novice runners have no experience and a four-mile run can be a big hurdle for a novice



runner. In this manner, by sustaining an injury it is likely that the runner thinks that the remaining training time is too short for him or her to be able to complete the four-mile run. A more experienced (recreational) runner may be able to listen properly to the language of his or her body, better than a novice runner. An experienced runner might also be able to feel or know that he or she is able to complete the race, even without the full eight weeks of training. Furthermore, an experienced runner is used to run on a regular basis and may be addicted to running, and therefore more likely to keep running.

Potential risk factors for RRI

Gender

The multivariate Cox regression model showed that male participants were at a higher risk than female participants. On the other hand, when gender was analysed univariately there was no significant relation with RRI. Macera^{6,21} stated that in population-based studies the injury rate was the same for male and female recreational and elite runners. This finding is in contrast with the results from a recent systematic review article on risk factors for RRI in long-distance runners, in which the only statistically significant association for overall lower extremity running injuries showed a positive relation with the female gender.¹⁸

Age and BMI

In the current study, younger age in male participants was positively associated with the risk of sustaining an RRI. This finding is supported by other studies which conclude that increasing age was significantly related with lower incidences of RRI.^{7,22} A reason for this phenomenon could be ‘the healthy runner effect’, whereby only those runners who stay injury-free continue to run.⁷ On the other hand, only 25% of the participants in our study population was already engaging in regular running. Other studies conclude that increasing age is a statistically significant risk factor for sustaining an RRI.^{1,23} Higher BMI is associated with sustaining an RRI in female participants. Heavier persons may have a higher risk of RRI due to the added physical stress of extra weight.²¹ Different associations between BMI and RRIs are found in the literature: Marti⁷ found that lower BMI (<19.5) and higher BMI (>27) were risk factors for development of an RRI.

Previous sports activities

Only females who were participating in sports activities without axial loading at baseline (for example cycling and swimming) were 1.8 times at higher risk (95% CI 1.1 to 3.2) than females participating in sports activities with axial load at baseline, that is, sports involving running and jumping. Other studies found no clear links between participation in other sports activities and development of RRI.^{7,8} The difference between our results and results from other studies could be caused by the fact that we categorised 'previous sports activities' into axial loading and non-axial loading.

Running experience

Lack of running experience was the most important risk factor for male and female participants in this study (HR 2.6 in males and 2.1 in females). In another study on RRI, participants who were running less than three years were 2.2 times at a higher risk compared to the more experienced ones.⁶ Review articles of van Mechelen² and Hoebregts²⁴ also state that running inexperience is a major risk factor for sustaining an RRI. Although they arrive at the same conclusion, caution is advised when making a comparison with our study, since in those studies running experience was assessed as the number of years engaging in running and the study populations were different compared to our study, i.e. had more running experience.

Previous injury of the lower extremity

No association was found between previous injury of the lower extremity and RRI. Hootman²⁵ stated that 'previous lower extremity injuries that were completely healed should not increase the risk for a subsequent lower extremity injury'. According to Taunton et al.,¹ of those with a previous injury 42% indicated not being completely rehabilitated before starting with the training program. It is not clear whether a high rate of re-injury suggests incomplete healing of the original injury, a personal susceptibility for re-injury, or an uncorrected biomechanical problem.²¹ A recent systematic review on incidence and determinants of lower extremity running injuries in long-distance runners showed strong evidence that a history of previous injuries was a risk factor for RRI.¹⁸ Again, most of the studies that were included consisted of participants engaging in long-distance running. Also, in most of the studies on risk factors for RRI it is not clear whether previous



injuries are about 'running-related' injuries of the lower extremity. If that is the case, a personal propensity for an uncorrected biomechanical problem could be the explanation.²¹

Conclusion

The incidence of RRI found in this study was 30.1 per 1,000 hours of running exposure. Of all runners at risk, 25.9% sustained an RRI during the eight-week period, and of those who sustained injury 39% did not restart running.

Male and female participants have different risk profiles. The study showed that for male recreational runners younger age and lack of running experience were significant risk factors for RRI. In female participants higher BMI, type of previous sports activities (non-axial loading) and having no running experience were all significant risk factors for sustaining a RRI during the eight-week follow-up. Male participants were more prone to sustain an RRI after correcting for age, BMI, previous sports activity, and running experience. The highest drop-out rate was seen in novice runners after sustaining an RRI. Care should be taken when interpreting this result as the study period was relatively short. Also, the gender-specific risk models for RRI showed that among both male and female participants, novice runners were the most at risk. These findings suggest that novice runners are the ones who may benefit most from preventive interventions for RRI.

What is already known on this topic:

Incidence of RRI in recreational runners is high.

What this study adds:

Accurate data collection of RRI and exposure resulted in more precise information on incidence of RRI in recreational runners and potential risk factors. This information gives health care providers the possibility to reach those runners who are most vulnerable for developing an RRI, i.e. novice runners.

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Chapter 4

The GRONORUN study: is a graded training program for novice runners effective in preventing running related injuries?

Design of a Randomized Controlled Trial

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Abstract

Background: Running is a popular form of recreational exercise. Beside the positive effects of running on health and fitness, the risk of a running related injury has to be considered. The incidence of injuries in runners is high and varies from 30-79%. However, few intervention studies on prevention of running related injuries have been performed and none of these studies involved novice runners.

Methods: GRONORUN (Groningen Novice Running) is a two armed randomized controlled trial, comparing the effects of two different training programs for novice runners on the incidence of running related injuries. Participants are novice runners, who want to train for a four mile running event. The control group will train according a standard 8 week training program. The intervention group will use a more gradual, 13 week training program which is based on “the ten percent training rule”. During the thirteen week follow up participants register information on running and RRI’s in an internet based running log. The primary outcome measure is RRI. An injury is defined as a musculoskeletal ailment of the lower extremity or back, causing a restriction of running for at least one week.

Discussion: The GRONORUN trial is the first randomized controlled trial to study a preventive intervention in novice runners. Many different training programs for novice runners are offered, but none are evidence based.

Trial Registration: ISRCTN37259753



Background

Worldwide, running is a sport practiced by many individuals to improve cardio-respiratory function, health and well-being.¹ The Royal Dutch Athletics Federation (KNAU) has estimated that around 12.5% of all Dutch people are running on a regular basis, and that the popularity of running events is still growing. The popularity of running positively contributes to increasing levels of physical activity in the population. This is important, because physical inactivity is associated with the development of several chronic diseases, decreased longevity, loss of physical function and weight control.² Running is a feasible way for people to become more active. To start with running, just a pair of shoes is needed.

Although running positively contributes to health, there is also the possibility of a running related injury (RRI). The incidence of RRI's injuries in runners at recreational and competitive level is high and varies from 30% to 79%.³⁻⁹ The wide range in incidence is caused by 1) differences in injury definition, 2) time of follow up, 3) differences in population at risk, and 4) differences in methods used to assess RRI, as well as exposure to running. Taking into account the exposure to running, an appropriate way to describe the incidence of RRI's is to calculate the number of RRI's per 1000 hours of running in the population at risk. Injury incidence per exposure varies from 7 to 59 per 1000 hours of running.^{3-5,10}

Most injuries in runners are overuse injuries of the lower extremity, caused by training errors, that is, running too much, too soon.¹¹ The exact cause and risk factors of RRI's are still unclear. However, it can be stated that the aetiology of these injuries is multifactorial and diverse. A review by Van Mechelen¹² proposed four factors that have been significantly related to running injuries: a) lack of running experience, b) previous injury, c) running to compete, and d) excessive weekly running distance.

Randomized controlled trials on the effect of interventions for preventing RRI in recreational runners are hard to find. A large amount of the information about the prevention of RRI's is derived from military recruits during basic training.¹³⁻²⁰ A Cochrane review on prevention of injuries in runners showed three categories of preventive strategies: 1) warming-up, cool down and stretching exercises, 2) use of external devices such as shock absorbing insoles, and 3) modification of training

schedule.²¹ Unfortunately, none of the interventions showed a significant effect in the prevention of RRI's.

Training is required to develop the ability to run. If the stress stimulus of running is optimal, a positive adaptation of structures will take place. An optimal stimulus along with an adequate recovery time will lead to an increase in strength.²² With the increasing ability to run, the structures ability to handle applied stress also increases.

To minimize the risk of a RRI, an increase of training duration or intensity by no more than 10% is recommended, i.e. the 10% rule.²³ However, so far no studies have examined the effect of such an increase of training load on injury risk in runners.

The GRONORUN trial is designed to examine the effect of a graded training program for novice runners on the incidence of running related injuries. In the current study, we hypothesize that when the human body gets more time for adaptation to running, the incidence of running related injuries will decrease. The objective of the GRONORUN trial is to evaluate the effectiveness of a 13-week graded training program, using the 10% rule, on the incidence of RRI's in a group of novice runners preparing for a four mile run compared to a commonly used 8-week training program. In this article we describe the design of the GRONORUN trial.

Methods/design

The GRONINGEN NOVICE RUNING (GRONORUN) study is a randomized controlled trial (RCT) with a thirteen week follow-up. Participants were randomized into an intervention group (13 weeks training program) or an active control group (8 week training program). Recruitment of participants for the GRONORUN trial took place in May and June 2005 and data collection started in July 2005. The intervention training program started in the second week of July, 13 weeks before the four mile running event, which took place in October 2005.

The study design, procedures and informed consent procedure were approved by the Medical Ethics Committee (Number 2004/285) of the University Medical Center Groningen (UMCG), The Netherlands. All participants provided written informed consent. Guidelines were followed according to the Consort Statement.²⁴



Study population

Recruitment was assisted by advertisements in local media to recruit participants who wanted to start a “beginners program” for the Groningen four mile recreational running event. It was not necessary to ultimately participate in the four mile running event itself. Potential participants were sent written information about the study along with a baseline questionnaire and an invitation for an initial interview at the Center for Sports Medicine of the UMCG.

Inclusion & exclusion criteria

Healthy participants between 18 and 65 years of age, who had no injury of the lower extremity in the three months prior to inclusion and who had not been running on a regular basis in the previous twelve months were eligible for inclusion in the study. Participants were excluded if there were absolute contraindications for vigorous physical activities according to the American College of Sports Medicine²⁵, or in case of unwillingness to keep a running log.

Sample size

A power calculation was carried out for the main outcome variable RRI, using a logistic rank survival power analyses. In other studies on novice runners incidence of RRI varies from 29.5 to 58% in a periods of respectively 13 to 28 weeks.^{3,8} For the GRONORUN trial we expected an injury incidence of 30%. With a hypothesized 25% reduction of RRI's in the intervention group compared to the control group, a total of 436 runners (2x218) were needed for a power of 80% and an alpha of 0.05. The hypothesized reduction was based on clinical relevance, because no other studies on the prevention of RRI in novice runners were found. Assuming an attrition of 15% in the intervention period, a total of 512 (2x256) novice runners were needed to detect an effect of the intervention.

Baseline measurements

Questionnaire

The baseline questionnaire consisted of five parts and was sent back by mail in a pre-paid envelope before the initial appointment at the hospital.

Part one covered demographic variables such as name, address, age, gender, and e-mail address.

Information about medical history was collected by the second part of the questionnaire. Conditions related to risk factors for cardiovascular diseases were assessed using a series of questions according to the American College of Sports Medicine.²⁵ Questions about previous musculoskeletal complaints of the lower extremity and back were assessed per anatomical site. Open-ended questions were used to obtain information about body height (in cm) and body weight (in kg). These self-reported body height and weight data were used to calculate BMI (weight (kg)/height²(m)).

Sports participation was assessed in part three by using questions concerning type of sport and mean hours of sports participation. Furthermore, a question on running experience in the past ("Have you ever participated in running on a regular basis?") was used to assess the novelty to running.

Part four consisted of the Jenkins Activity Survey (JAS). The JAS is a tool to indicate type A behaviour.²⁶ Individuals with a pronounced type A behaviour, also referred to as coronary prone behaviour, are possibly more prone to injury.²⁷ Type A behaviour is characterized by above average achievement drive, aggressiveness, hostility, impatience, time urgency, and competitiveness.²⁶

Part five assessed the motivation for running, using a Dutch translated version of the Motivation Of Marathoners Scale (MOMS). The MOMS is an instrument that measures the motives of runners, by means of 56 items distributed across nine scales. Content areas covered include health orientation, weight concern, self-esteem, life meaning, psychological coping, affiliation, recognition, competition, and personal goal achievement. The MOMS was validated by Masters²⁸, and demonstrated an adequate internal consistency (Cronbach's alpha range .80 to .93), retest reliability (intraclass correlations range .71 to .90), and factorial validity of the scales.



Initial interview

During the initial interview at the UMCG all participants were seen by a sports medicine physician. The purpose of the initial interview was to screen for cardiovascular diseases and abnormalities of lower limb and, to ensure that the participants were adequately informed about the study before signing informed consent.

Orthopedic examination

An universal goniometer with arm length 30 cm from axis to tip was used to measure all range of motions with recordings in increments of 1.0° . The internal and external range of motion of the hip was assessed with the participant supine and the tested hip and knee flexed to 90° . Knee flexion and extension ranges of motion were assessed with the participant in supine position. The goniometer was placed on the lateral aspect of the knee, with the axis of the goniometer in line with the greater trochanter and the lateral malleolus. Ankle plantarflexion and dorsiflexion were measured both with the knee fully extended and flexed to 90° . One arm of the goniometer was aligned with the fibular bone and the other with the plantar surface of the foot. Furthermore, the navicular drop was assessed by measuring the change in the height of the navicular tuberosity between a participant sitting with the subtalar joint in neutral position and participant standing, weight bearing with the subtalar joint in relaxed stance, as described by Brody.²⁹ The navicular drop is a valid method to indicate the amount of foot pronation.³⁰ Intratester and intertester reliability of this technique is ranging from .73 to .96.³¹ Measurements were made twice for each foot, with results being averaged.

Randomization

After baseline measurements and informed consent, participants were assigned to the intervention training program or the control training program. To ensure that both training groups were equal in terms of injury risk, a stratified randomization was performed. Participants were stratified for current sporting activities status, previous injury, and gender. Based on sporting activities, there are three categories of novice runners. The first category consists of novice runners who already are participating in a sport in which axial load (i.e., running, walking or jumping) is

integrated. The second category is formed by novice runners who already are participating in sporting activities without axial load, like swimming and cycling. The third category is formed by novice runners who did not participate in any sporting activities at baseline measurements. In a study by Macera⁶, a 74% increased risk was found in runners with a positive history of previous injuries. Since it is not clear whether the high rate of re-injury is caused by incomplete healing of a previous injury or a biomechanical problem, a differentiation in time is made. A distinction can be made between no previous injury, sustaining injured in the last 12 months before baseline measurements, and sustaining injured more than 12 months before baseline measurements. Eighteen strata were formed by gender, previous injury (no, 3-12 months and > 12 months) and sporting activities (no, with axial load and without axial load). From each stratum participants were allocated to intervention or control group by drawing a sealed opaque envelope. Each stratum box contained equal numbers of control and intervention envelopes.

Participant flow

The study design and participants flow are shown in Figure 1. A total of 603 people were interested to participate in the GRONORUN trial and reacted on the call for novice runners. All of those who responded to the advertisements were sent an information package containing: a brochure in which the study protocol was clearly described, a baseline questionnaire, and an appointment at the UMCG. Twenty three did not confirm their appointment for the initial appointment nor sent back the baseline questionnaire. Of those who confirmed the appointment for the initial appointment and sent back the questionnaire (n=580), twenty five failed to attend the initial appointment. Of 555 persons who visited the UMCG for an initial appointment, 23 were excluded. Reasons for exclusion were: already participating in running (8), musculoskeletal injury of lower extremity or back at baseline (13) and contraindications for vigorous physical activity (2). After baseline measurements and stratification, 532 persons were randomly assigned to the intervention group (n=264) and to the control group (n=268).

Training program

All participants received the same general written and oral information on intensity of running and on warming up and cooling down. Participants were instructed to



walk brisk for 5 minutes as a warm up, and 5 minutes as cool down. Given that the best available evidence indicates that stretching before or after exercise does not prevent muscle soreness or injury³², participants were instructed not to perform stretching exercises before, during or after the training sessions.

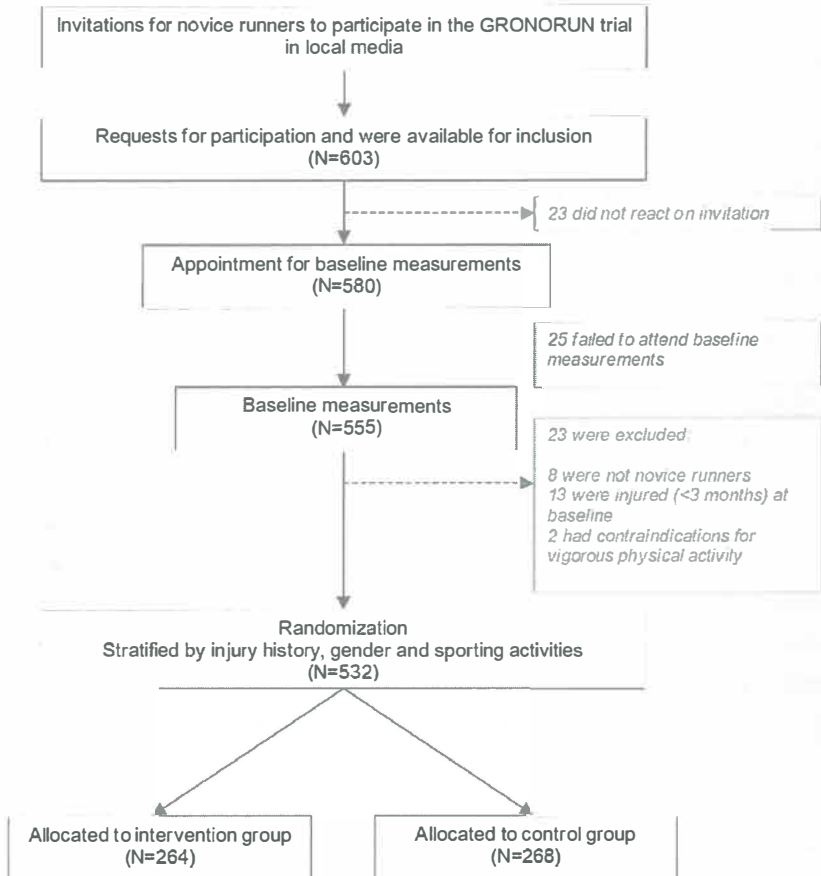


Figure 4.1 – GRONORUN flow chart

The frequency of running was equal in both groups. Each training week, except the last week, that is, the week of the four mile run, consisted of three training sessions represented by a combination of running and walking. Participants were encouraged to run on Monday, Wednesday, and Saturday, and were advised to run at a comfortable pace at which they could converse without breathlessness. Both groups trained individually, without a trainer, on a self-chosen course.

Control group: 8 week training program

The novice runners in the control group received a frequently used beginners training program to prepare for a four mile run. The program started 8 weeks before the start of the Groningen four mile run at the level of a run-walk session with a total of 10 minutes of running and 10 minutes of walking (see Table 4.1).

Table 4.1: - 8-week-training program for the control group.

	training 1			training 2			training 3			total	
	run	walk	(rep.)	run	walk	(rep.)	run	walk	(rep.)	run	walk
week 1	1	1	(10)	1	1	(10)	1	1	(10)	30	30
week 2	4	2	(4)	4	2	(4)	4	2	(3)	46	22
week 3	6	2	(3)	12	3	(2)	6	2	(3)	60	18
week 4	6	2	(3)	7	2	(2)	6	2	(3)	50	16
week 5	10	2	(2)	17	4	(2)	10	2	(2)	74	16
week 6	15	5	(2)	20	5	(2)	20	0	(1)	90	21
week 7	40	0	(1)	30	5	(1)	25	0	(1)	95	5
week 13	30	0	(1)								

The content of each training session is expressed in minutes of running (run), minutes of walking between the running sessions (walk) and number of repetitions (rep.). The right column contains total minutes of running and walking of each week.

Intervention group: 13 week training program

The intervention group started the 10% rule training program 13 weeks before the start of the Groningen four mile running event (see Table 4.2). Gradual increase of training load, that is, time of running was 10% per week and the ratio between running and walking was also increasing. The starting point of the program was exactly the same as the start of the program of the control group (i.e., ten minutes of running, interchanged with walking).



Table 4.2: - 13-week-training program for the intervention group.

	training 1			training 2			training 3			total	
	run	walk	(rep.)	run	walk	(rep.)	run	walk	(rep.)	run	walk
week 1	1	1	(10)	1	1	(10)	1	1	(10)	30	30
week 2	2	1,5	(5)	2	1,5	(7)	2	1,5	(7)	34	25,5
week 3	3	2	(4)	3	2	(4)	3	2	(4)	36	24
week 4	4	2	(3)	4	2	(4)	4	2	(3)	40	20
week 5	4	2	(4)	4	2	(4)	4	2	(3)	44	22
week 6	6	2	(3)	6	2	(3)	6	2	(2)	48	16
week 7	6	2	(3)	9	3	(2)	6	2	(3)	54	18
week 8	6	2	(3)	6	2	(3)	10	3	(2)	56	18
week 9	8	2	(3)	12	0	(1)	14	4	(2)	64	14
week 10	10	2	(2)	16	5	(2)	10	2	(2)	72	18
week 11	15	5	(2)	30	0	(1)	20	5	(2)	80	15
week 12	30	0	(1)	20	0	(1)	40	0	(1)	90	0
week 13	30	0	(1)								

The content of each training session is expressed in minutes of running (run), minutes of walking between the running sessions (walk) and number of repetitions (rep.). The right column contains total minutes of running and walking of each week.

Outcome measures

The primary outcome of the GRONORUN trial is the number of RRI's in both groups. Definition of a RRI in this trial is; running related musculoskeletal ailment of the lower extremity or back, causing a restriction of running for at least one week, that is, three consecutive training sessions.

Information on RRI's and exposure data were collected using an internet based running log. Each of the participants received a study number and a password to enter a personal environment of the internet based training log. After each training week participants had to fill in their running activities, other sport activities and injuries.

Per training session the total minutes of running, total minutes of walking, and injuries were registered. Data on injuries were collected by registering anatomical site of the body and severity of pain. Severity of pain was subdivided in pain without limitation (no RRI), pain that caused a restriction of running (RRI), and running impossible through RRI (RRI). In case of skipping a training session, the

reason (RRI, other injury, motivation, illness, or remaining reason) for it was asked. When a “running related injury” was the reason for not running, information on anatomical site and severity was asked. A picture of the lower body was used to assess the anatomical site of the RRI. By clicking on the anatomical site, the area of the RRI was red appointed. When participants did not enter their digital training log after one week, a reminder was sent by email automatically.

Statistical analyses

To evaluate the success of the randomization, baseline values will be analyzed for differences between intervention group and control group, using a chi-square for categorical data and a student’s t-test for numerical data. To analyze the primary outcome (i.e., RRI), the Kaplan-Meier method will be used. Once a participant has a RRI his or her survival time will be terminated. To evaluate the effect of the intervention, a log rank test will be used to compare the Kaplan-Meier curves of the intervention group to the control group. Analyses will be performed following the “intention to treat” principle. Differences will be considered statistically significant at $p < 0.05$. All analyses will be done using SPSS version 12 (SPSS, Chicago, Illinois).

Discussion

The GRONORUN trial is the first randomized controlled trial to study the effect of a modification of a training program on RRI’s in novice runners. There is a need for well controlled trials about preventive interventions in running populations because of the popularity of running and the high rates of RRI’s.

Novice runners are often physically inactive before they start to run. The health benefits in this previously physically inactive group can be high. On the other hand, lack of running experience is one of the risk factors for a RRI.⁶ The major reason for discontinuation (drop out) of a running program is injury.³³ Negative experiences, caused by an injury that occurs while training for a running event, have the potential to significantly affect the future physical activity of each individual.³⁴ It is also known that (fear of) sustaining an injury is associated with failure to start and maintain a physically active lifestyle.³⁴ So, prevention of injuries in novice runners is important.



On the internet and in running shops different training programs for novice runners are available. Most of the programs are based on expert opinion. There are numerous “experts” and they all have their own opinion of “the best running program”, however none of them are based on scientific evidence.

As a result of the GRONORUN trial, valuable information will be gained on training programs for novice runners. With this new information on training programs, it might be possible to reduce the incidence of RRI’s in future.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

SW conceived of the idea, obtained funding for the study, and developed the intervention. SW and IB developed the design of this trial, and recruited participants. WM provided advice on the study design and contributed to the content of the article. IB is the study investigator, was responsible for data acquisition, and wrote the article. KL and RD are co applicants of the grant. JZ and GJP contributed to the content of the article. All authors read and approved the final manuscript.

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Chapter 5

No Effect of a Graded Training Program on the Number of Running-Related Injuries in Novice Runners: A Randomized Controlled Trial

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Abstract

Background: Although running has positive effects on health and fitness, the incidence of a running-related injury (RRI) is high. Research on prevention of RRI is scarce; to date, no studies have involved novice runners.

Hypothesis: A graded training program for novice runners will lead to a decrease in the absolute number of RRIs compared with a standard training program.

Study Design: Randomized controlled trial; Level of evidence, 1.

Methods: GRONORUN (Groningen Novice Running) is a 2-armed randomized controlled trial comparing a standard 8-week training program (control group) and an adapted, graded, 13-week training program (intervention group), on the risk of sustaining an RRI. Participants were novice runners ($N = 532$) preparing for a recreational 4-mile (6.7-km) running event. The graded 13-week training program was based on the 10% training rule. Both groups registered information on running characteristics and RRI using an Internet-based running log. The primary outcome measure was RRIs per 100 participants. An RRI was defined as any musculoskeletal complaint of the lower extremity or back causing a restriction of running for at least 1 week.

Results: The graded training program was not preventive for sustaining an RRI ($\chi^2 = 0.016$, $df = 1$, $P = .90$). The incidence of RRI was 20.8% in the graded training program group and 20.3% in the standard training program group.

Conclusions: This randomized controlled trial showed no effect of a graded training program (13 weeks) in novice runners, applying the 10% rule, on the incidence of RRI compared with a standard 8-week training program.

Keywords: running-related injuries; incidence; prevention; training program; novice runners



Introduction

Running is a sport practiced by many individuals to improve cardiorespiratory function, health, and well-being. In conjunction with the positive effects of running on health and fitness, it is important to consider the risk of a running-related injury (RRI). Research has shown that the incidence of RRI is high; incidence rates of RRI vary from 30% to 79%,¹⁻⁷ and from 7 to 59 RRIs per 1000 hours of running.^{1-3,8}

Most RRIs are overuse injuries of the lower extremity.⁹ The causes of these overuse RRIs are multifactorial.⁹ Four factors have been related consistently to running injuries: (1) lack of running experience, (2) previous injury, (3) running to compete, and (4) excessive weekly running distance.¹⁰ It is estimated that 60% of all RRIs can be attributed to training errors, that is, running too much too soon.⁹

Little research has been performed on the prevention of RRI in the running population. Several controlled studies on the prevention of RRI exist.¹¹⁻²⁰ However, to our knowledge, there are no studies that have examined the effect of a preventive intervention on RRI in novice runners.

The principle that the volume of exercise should be increased gradually over time is widely regarded as critical for reducing the risk of an overuse injury.²¹ This general principle is also applicable in running. To minimize the risk of RRI, an increase in training volume by no more than 10% a week is mentioned; this is called the 10% rule.²² In a training program based on the 10% rule, the body is thought to adapt more gradually to the external impact forces of running. However, so far no studies have examined the effect of such a modified training program on the injury incidence in novice runners.

Therefore, the aim of the Groningen Novice Running (GRONORUN) study was to determine the effect of a modified (ie, graded) training program for novice runners, based on the 10% rule, on the incidence of RRI. We hypothesized that when the human body gets more time for adaptation to running, the incidence of RRI will decrease.

Methods

Design

The GRONORUN study is a randomized controlled trial with a 13-week follow-up (ISRCTN37259753). A description of the design of the GRONORUN trial is published elsewhere.²³ Participants were randomized into an intervention group (13-week graded training program) or a control group (an 8-week standard training program). The study design, procedures, and informed consent procedure were approved by the Medical Ethics Committee of the University Medical Center Groningen, The Netherlands. All participants provided written informed consent. Guidelines according to the Consort Statement were followed.²⁴

Participants and Randomization

Recruitment was assisted by advertisements in local media to enlist participants who wanted to start a "beginners program" in preparing for the Groningen 4-mile recreational running event. To participate in the beginners program, it was not necessary to ultimately participate in the 4-mile running event itself. Healthy participants between 18 and 65 years of age, who had not sustained an injury of the lower extremity in the last 3 months before inclusion and who had not been running in the previous 12 months, were eligible for inclusion in the study. Participants were excluded if there were absolute contraindications for vigorous physical activities according to the American College of Sports Medicine²⁵, or in case of unwillingness to keep a running log.

After baseline measurements and informed consent, participants were assigned to the graded training program or the standard training program. To ensure that both training groups were equal in terms of a priori injury risk, a stratified randomization was performed. Participants were stratified for current sporting activities status (no sport, axial loading sports, nonaxial loading sports), previous injury (none, 3–12 months ago, >12 months ago), and gender. From each stratum, participants were allocated to the graded training program or standard training program group by drawing a sealed opaque envelope.



Baseline Measurements

The baseline questionnaire covered demographic variables such as age, gender, body weight, and height. Previous musculoskeletal complaints of the lower extremity and back were assessed per anatomical site. Current sports participation was assessed by questions concerning type of sport and mean hours of sports participation. Furthermore, a question on running experience in the past ("Have you ever participated in running on a regular basis?") was used to assess the novelty to running.

Training Program

All participants received the same general written and oral information. They were instructed to walk for 5 minutes as a warm-up and cool-down. Both groups trained individually 3 times a week, on a self-chosen course and surface. All were advised to run at a comfortable pace at which they could converse without losing breath. The graded training group and the standard training group started, respectively, 13 and 8 weeks before the Groningen 4-mile run. In training sessions, combinations of running and walking were used (Table 5.1).

Table 5.1: Training Program in Minutes Per Week for the Graded Training Program Group and the Standard Training Program Group

	Graded Training Group		Standard Training Group	
	Run (min/wk)	Walk (min/wk)	Run (min/wk)	Walk (min/wk)
Week 1	30	30		
Week 2	34	25.5		
Week 3	36	24		
Week 4	40	20		
Week 5	44	22		
Week 6	48	16	Week 1	30
Week 7	54	18	Week 2	46
Week 8	56	18	Week 3	60
Week 9	64	14	Week 4	50
Week 10	72	18	Week 5	74
Week 11	80	15	Week 6	90
Week 12	90	0	Week 7	95
Week 13	30	0	Week 8	30

Outcome Measures

The primary outcome measure of the GRONORUN trial is the absolute number of RRIs, expressed per 100 runners. An RRI was defined as any musculoskeletal complaint of the lower extremity or back causing a restriction of running for at least 1 week. The effect of the graded training program was evaluated by the differences between proportions of injured runners in both groups. Additional analyses were done on the time until an event (RRI), the number of RRIs per 1000 hours of exposure in both groups, and the anatomical distribution of RRIs. Information on RRI and exposure data was collected using an Internet-based running log. If an RRI was the reason for not adhering to the training program, information on anatomical site and severity was asked. When participants did not enter their Internet-based training log after 1 week, a reminder was sent by e-mail automatically. Participants who dropped out of the program and who did not complete their entire running log were contacted by a research assistant to ensure that RRI was not the reason for dropping out.

Statistics

A power calculation was carried out for the main outcome variable RRI using a logistic rank survival power analysis. For the GRONORUN trial, we expected a baseline injury incidence of 30%.²³ With a hypothesized 25% reduction of RRI in the graded training program group compared with the standard training program group, a total of 436 runners (2 x 218) were needed for a power of 80% and an alpha of 0.05.²³ Assuming an attrition of 15% in the intervention period, a total of 512 (2 x 256) novice runners were needed to detect an effect of the intervention.

Baseline characteristics of participants in the graded training program group and standard training program group were compared using 2-tailed t tests for normally distributed continuous variables. The χ^2 statistic was used for discrete variables. To evaluate the effect of the graded training program on RRI, a χ^2 test was used. The log-rank test is used to compare the Kaplan-Meier curves of the graded training program group and the standard training program group, analyzing the difference between the training groups in the probability of an RRI at any time point. Cox proportional hazards regression analysis was performed to correct for differences in body mass index (BMI) between randomized groups at baseline. All analyses were



performed following the "intention to treat" principle. Differences were considered statistically significant at $P < .05$. All analyses were performed using SPSS version 12.0 (SPSS Inc, Chicago, Ill).

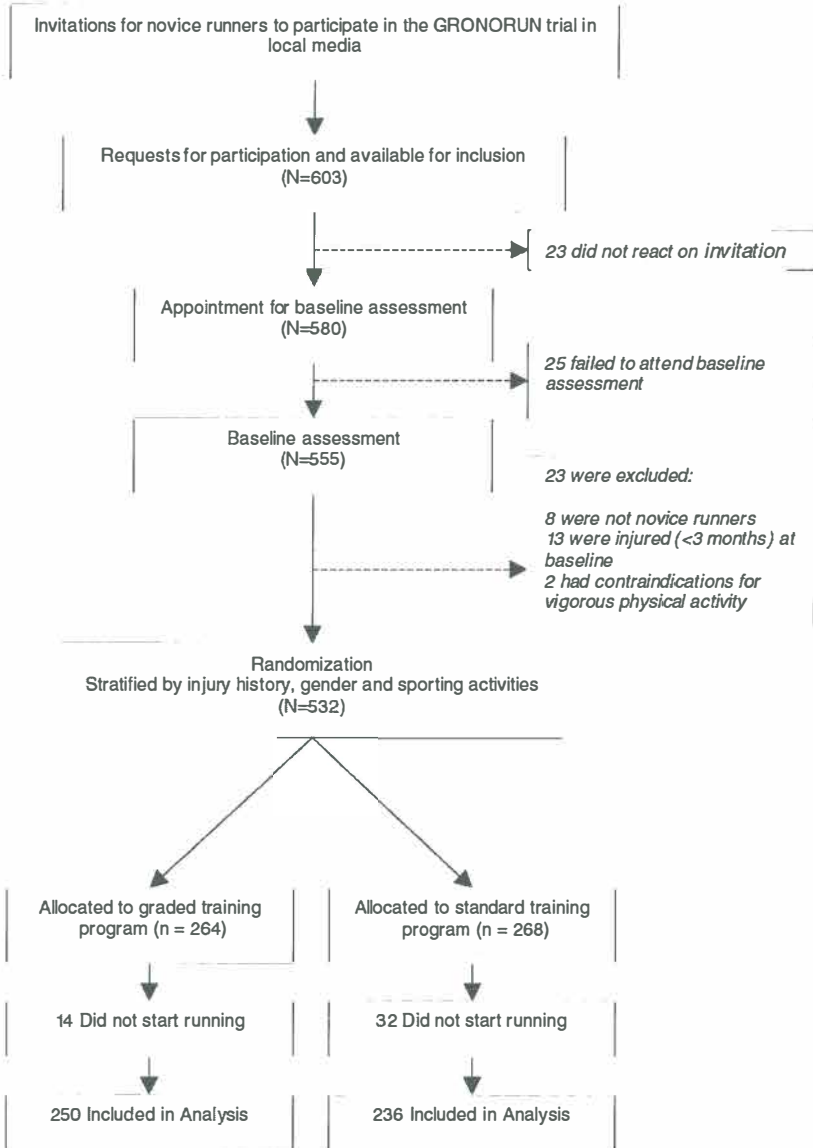


Figure 5.1: The flow of participants through each stage of the GRONORUN (Groningen Novice Running) trial.

Results

Randomization/Sample Attrition

The flow of participants is shown in Figure 5.1. An information pack about the GRONORUN study and an appointment for a baseline assessment were sent to a total of 603 volunteers. Twenty-three (3.8% of 603) did not react on the invitation and another 25 (4.1% of 603) failed to attend the baseline assessment. Among those participants who attended the baseline assessment, 23 of 555 (4.1%) were excluded because they did not meet the study eligibility criteria. Thus, 532 novice runners were randomized into the graded training program group and the standard training program group. A participant was lost to follow-up (ie, excluded from the final analysis) if she or he did not start running or if no exposure data were available. Significantly more participants of the standard training program group were lost to follow-up because they did not start running—32 of 268 (11.9%) versus 14 of 264 (5.3%) of the graded training program group.

Table 5.2: Baseline Characteristics of Participants in Graded Training Program and Standard Training Program Groups

Characteristic	Dimension/Qualifier	Graded Training Program	Standard Training Program	Total
n		264 (113 men, 151 women)	268 (113 men, 155 women)	532 (226 men, 306 women)
Age ^b	Years	40.4 (10.0)	39.2 (10.2)	39.8 (10.1)
Weight ^b	Kg	78.7 (13.9)	77.0 (14.2)	77.8 (14.0)
BMI ^{bc}	kg/m ²	25.2 (3.7)	24.6 (3.2)	24.9 (3.5)
Running experience	No	131 (49.6%)	119 (44.4%)	250 (47.0%)
	Yes	133 (50.4%)	149 (55.6%)	282 (53.0%)
Previous injury	No	131 (49.6%)	127 (47.4%)	258 (48.5%)
	>3, ≤12 months ago	69 (26.1%)	66 (24.6%)	135 (25.4%)
	>12 months ago	64 (24.2%)	75 (28.0%)	139 (26.1%)
Sporting activities	No	130 (49.2%)	119 (44.4%)	249 (46.8%)
	With axial load	70 (26.5%)	79 (29.5%)	149 (28.0%)
	Without axial load	64 (24.2%)	70 (26.1%)	134 (25.2%)

^aBMI, body mass index.

^bValues are mean ± standard deviation (in parentheses)

^cP < .05



The baseline characteristics of participants in the graded training program group and the standard training program group, including the variables that were used for stratification, are provided in Table 5.2. Of the 532 randomized participants, 306 (57.5%) were female. Forty-seven percent of all randomized participants had never run on a regular basis before. Randomization groups were not similar in BMI. The graded training program group showed a small (25.2 vs 24.4 kg/m²), but significantly higher ($P < .05$), difference in BMI. As shown in Table 5.2, running experience and activity level were not the same in all participants but were equally distributed over both training groups.

Effect of the Graded Training Program

The incidence of RRI was 20.8% (52 of 250) in the graded training program group and 20.3% (48 of 236) in the standard training program group. The graded training program was not preventive for sustaining an RRI ($\chi^2 = 0.016$, $df = 1$, $P = .90$). Because the exposure to running in both training groups was not equal, survival curves (ie, Kaplan-Meier curves) were made for both training groups (Figure 5.2A). Figure 5.2B shows the survival curves of injured participants in the standard training group and the graded training group. The mean survival time of injured runners in the graded training group was 212 minutes (standard deviation [SD] = 160), compared with 167 minutes in the standard training group (SD = 153). The log-rank test showed no difference between the graded training program group and the standard training program group ($P = .18$). Cox regression analyses, adjusted for BMI, revealed no significant effect of the graded training program on injury risk (odds ratio [OR] = 0.8; 95% confidence interval [CI], 0.6–1.3).

Table 5.3: Incidence of RRI per 100 Runners at Risk and per 1000 Hours of Running Exposure in Graded and Standard Training Program Groups

	Graded Training Program (n = 250)	Standard Training Program (n = 236)	Total (N = 486)
Absolute number of RRIs ^a	52	48	100
RRI/100 runners at risk ^b	20.8 (15.8–25.8)	20.3 (15.2–25.4)	20.6 (17.0–24.2)
RRI/1000 hours of exposure ^b	30 (22–38)	38 (27–49)	33 (27–40)

^a RRI, running-related injury.
^b Numbers in parentheses represent 95% confidence interval.

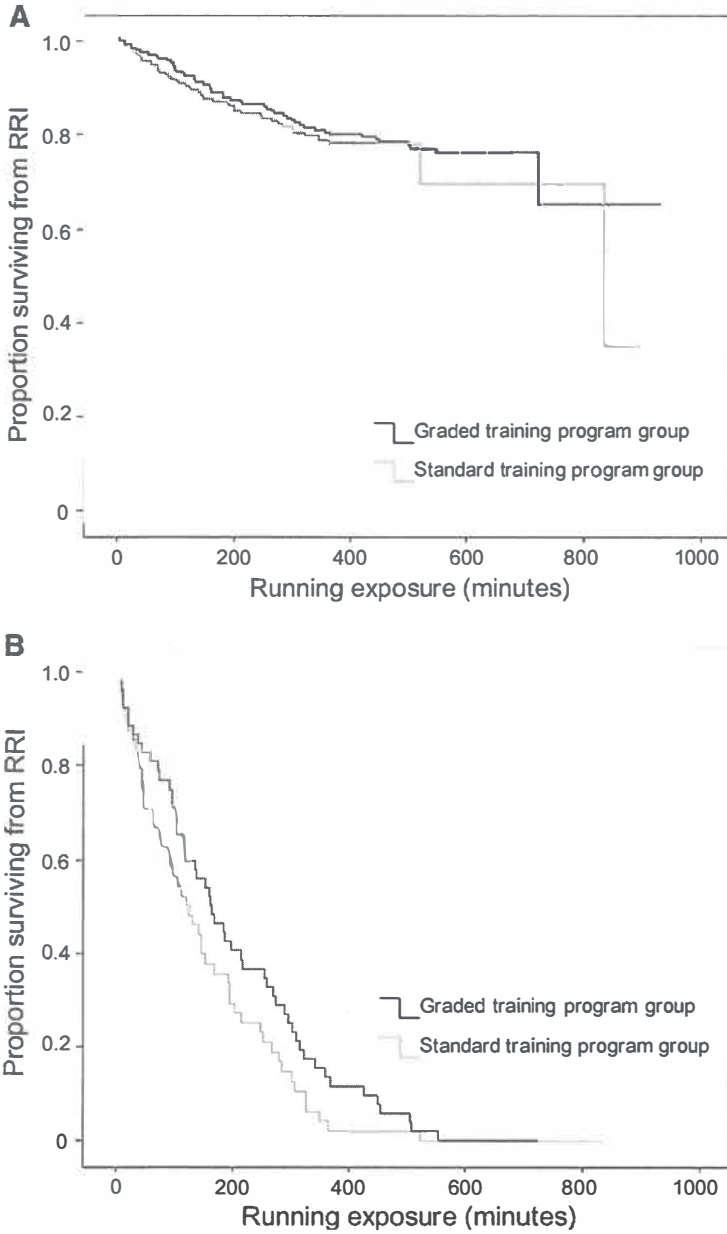


Figure 5.2. A, Kaplan-Meier plot of RRI (running-related injury) survival between all participants of the graded training program group and standard training program group. Approximately 80% in both groups stayed injury free. B, Kaplan-Meier plot of RRI survival between injured participants of the graded training program group and standard training program group.



Occurrence of Running-Related Injuries

Altogether 100 RRIs were recorded: 52 in the graded training program group and 48 in the standard training program group. A summary of injury incidence is provided in Table 5.3.

The absolute number of RRIs per week in each training group is illustrated in Figure 5.3. In the first 7 weeks of the standard training program, 47 RRIs were registered, compared with 34 in the graded training program (relative risk [RR] = 1.38). Most of the RRIs in the graded training program group were seen in the fifth week of the program. In this training week, the participants ran 44 minutes (see Table 5.1). In the standard training program group, most of the injuries were seen in the second week, when participants had to run 46 minutes. Descriptive information on RRIs is shown in Table 5.4. The most frequently injured body parts were the lower leg (40%) and the knee (37%).

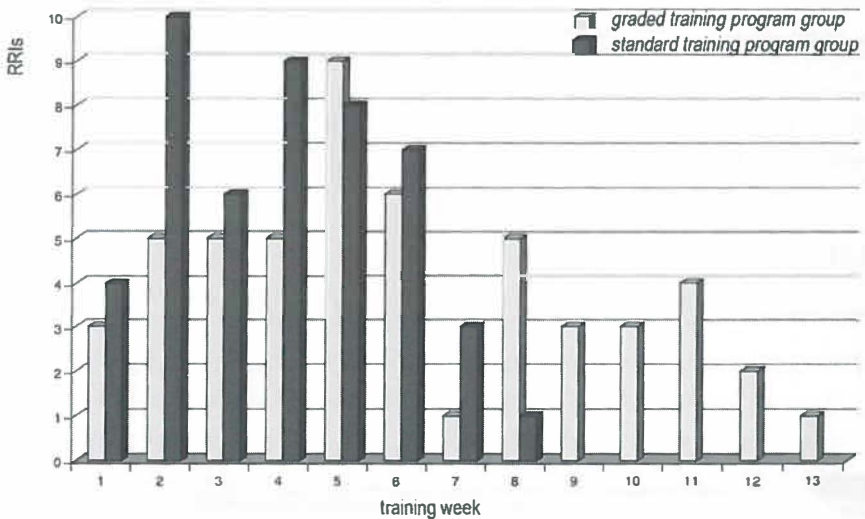


Figure 5.3. The absolute number of new running-related injuries (RRIs) per group in each week of the training program.

Table 5.4: Absolute Number and Percentage of RRIs per Anatomical Site per Group

	Graded Training Program, n = 250 (% of RRIs)	Standard Training Program, n = 236 (% of RRIs)	Total N = 486 (% of RRIs)
Hip/back	6 (11.5%)	3 (6.3%)	9 (9%)
Upper leg	2 (3.8%)	2 (4.2%)	4 (4%)
Knee	17 (32.7%)	20 (41.7%)	37 (37%)
Lower leg	22 (42.3%)	18 (37.5%)	40 (40%)
Ankle/foot	5 (9.6%)	5 (10.4%)	10 (10%)
Total	52 (100%)	48 (100%)	100 (100%)

^aRRIs, running-related injuries.

Compliance with the Program

Compliance with the program was expressed in the proportion of recommended training sessions. The graded training program group completed 24.6 ± 11.2 training sessions during the intervention period (66.4% of the recommended volume). The compliance in the standard training program group (64.5% of the recommended volume) was comparable with that of the graded training program group. Compliance with the program was 70.6% in the graded training program group and 69.0% in the standard training program group if only the noninjured participants were taken into account.

Discussion

The GRONORUN trial was designed to study the effect of a graded (ie, 10%) training program on the incidence of RRIs. The results showed no significant effect of the more gradual increase of running on the number of RRIs per 100 runners at risk compared with a standard 8-week training program. On the basis of these results, our hypothesis—that when the human body gets more time for adaptation to running, the incidence of RRIs will decrease—should be rejected.

To explain the absence of an effect, a variety of reasons are discussed. A dose-response relationship has been described between running (duration, intensity), recovery time (frequency per week), and strengthening (or, when the load is too much, weakening) of the musculoskeletal system.²⁶ Repeatedly applied stress leads



to positive remodeling of musculoskeletal tissue if sufficient time is provided between stress applications. Adequate recovery time (ie, time between the training sessions) will result in a positive adaptation of the musculoskeletal system to an adequate stress stimulus of running. Hreljac²⁷ called this phenomenon the stress-frequency relationship. Given this relationship, various reasons for the absence of an effect in the current study are conceivable.

First, the contrast in duration of running (ie, minutes per week) between the 2 training programs (graded vs standard) may have been too small to cause an effect. This is a hypothesis that can be studied by adapting (lengthening) the graded training program in a future study. On the other hand, if participants who are allocated to the control group have to wait too long to start running, the number of participants lost to follow-up probably would become too high. Second, the intensity of running might have been a confounding factor. Although the participants in both groups were advised to run only at a comfortable pace at which they could converse without breathlessness, we did not measure the intensity of running. Third, the absence of an effect may have been caused by the similarity of weekly running frequency in both groups. With reference to the dose-response relationship in running, it may not only be the absolute training duration per week but also the intensity of the training sessions as well as the frequency that need to be taken into consideration. When there is inadequate time between stress applications, an overuse injury can occur.^{9,28}

Additional analyses showed that the number of RRIs per 1000 hours of running exposure was 30 (95% CI, 22–38) in the graded training program group versus 38 (95% CI, 27–49) in the standard training group. Even though this seems a disparity, the number of RRIs per 1000 hours of exposure was not significantly different. Care should be taken when interpreting this result as the study was not set up in a way that could identify such an effect size. It takes many more participants than we had to identify an effect expressed in the number of RRIs per 1000 hours of exposure to running. The results of the additional analyses on survival time also showed no differences between the graded training program group and the standard training group. Although the mean time to the occurrence of an RRI was 45 minutes longer (212 vs 167 minutes) in participants of the graded training program, this difference in exposure time was not significant.

In the literature, little information is available on the incidence of RRI in novice runners. In the GRONORUN trial, the overall incidence of RRI was 20.6 per 100 runners. Differences in the definition of RRI, as well as the way of collecting information on RRI, make it difficult to compare the GRONORUN study with another. Furthermore, only few of the studies in the literature followed runners for a comparable short period of time.

The "Vancouver Sun Run" study⁶ showed an injury incidence of 29.5 per 100 runners at risk in a group of novice runners following a 13-week training program, preparing for a 10-km running event. The training program of the Vancouver Sun Run⁶ was designed by sports physicians to minimize the risk of sustaining an injury during the training period. The recommended running frequency was identical to that used in the GRONORUN trial, that is, 3 times a week. Unfortunately, neither the content nor the rationale for the program was reported.

Comparison of the incidence of RRI in the GRONORUN study to the Vancouver Sun Run study is complicated by differences in definition of an RRI. In the Vancouver Sun Run study, a runner was defined injured in case of reporting running-related pain during or after running. In our trial, severity (ie, restriction of running) and a minimal duration of 1 week was added. If our definition was changed in to the definition used by Taunton et al,⁶ the number of RRIs would be 34.3 per 100 runners at risk—higher than in the Vancouver Sun Run study.

A second study that also involved runners with little or no running experience showed an incidence of 58 RRIs per 100 runners at risk.¹ In this study, participants trained for a 15-km run during the first period of 28 weeks. Any running-related pain causing restriction in running distance, speed, duration, or frequency was considered to be an injury. When the overall incidence per 1000 hours of running exposure is compared with data from the literature, it can be concluded that the incidence was higher (33/1000 hours) than that reported in the literature (12/1000 hours).¹ A significant difference between this study and the GRONORUN trial is that participants were intending to run a marathon at the end of the training period of 20 months. In the GRONORUN trial, participants were recruited only to train for a 4-mile run.

As shown in other studies, over 75% of the RRIs were localized from the knee and below.^{1,5,6} The anatomical distribution of RRIs in the GRONORUN trial was in



agreement with these findings, that is, the knee (37%) and the lower leg (40%) were the most injured body parts.

Prevention of RRIs is an important issue in sports medicine. Running, as a form of recreational exercise, is a sport practiced by many individuals to improve cardiorespiratory function and health. Novice runners are often physically inactive before they start to run. In the Vancouver Sun Run study⁶ and our study, almost half of the participants were primarily sedentary and deconditioned people. On the Internet and in running stores and running magazines, many so-called "training programs for novice runners" preparing for a 5-km or 10-km running event in a relatively short period of time can be found. To prevent RRIs, which still happen in 20% to 50% of the novice runner population, the current results show that more research is needed on the relationship between intensity, frequency, and the duration of training and injury risk, and other potentially possible modifiable risk factors. In a future study, the intervention duration should be lengthened, taking the increase of weekly product of running frequency, intensity, and duration into careful consideration.

Conclusions

This study showed that there is no effect of a graded "10% rule" training program for novice runners on the number of RRIs per 100 runners at risk, compared with a standard training program. We hypothesized that novice runners need adequate time for the musculoskeletal system to adapt to running. Preparing to participate in a 4-mile run, it does not matter how you get there (either fast or slow)—the risk of sustaining an RRI is the same. Future research should focus on the dose-response relationship between running and the development of RRIs in (novice) recreational and competitive runners.

Acknowledgments

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Chapter 6

Predictors of Running-Related Injuries in Novice Runners: A prospective cohort study

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ABSTRACT

Background: The popularity of running is still growing. As participation increases running related injuries also increase. Until now, little is known about the predictors for injuries in novice runners.

Hypothesis: Predictors for Running-Related Injuries (RRI) will differ between male and female novice runners.

Study Design: Prospective Cohort study.

Methods: Participants were 532 novice runners (226 men, 306 women) preparing for a recreational 4-mile (6.7-km) running event. After completing a baseline questionnaire and undergoing an orthopedic examination, they were followed during the training period of thirteen weeks. An RRI was defined as any self-reported running-related musculoskeletal pain of the lower extremity or back, causing a restriction of running for at least one week.

Results: Twenty-one percent of the novice runners had at least one RRI during follow-up. The multivariate adjusted Cox regression model for male participants showed that BMI per $\text{kg} \cdot \text{m}^{-2}$ (HR 1.15; 95% CI 1.05–1.26), previous injury in the past year (HR 2.7; 95% CI 1.36–5.55) and previous participation in sports without axial load (HR 2.05; 95% CI 1.03–4.11) were associated with RRI. In female participants only navicular drop (HR 0.85; 95% CI 0.75–0.97) remained a significant predictor for RRI in the multivariate Cox regression modeling. Type-A behavior and range of motion (ROM) of the hip and ankle did not affect risk.

Conclusion: Male and female novice runners have different risk profiles. Higher BMI, previous injury and previous sports participation without axial loading are important predictors for RRI in male participants. Further research is needed to detect more predictors for female novice runners.

Clinical Relevance: Clinicians may use this information to appropriately inform the novice runners about the risk of an RRI when starting to run.



Background

Recreational running is a popular way to become or stay physically active. In the Netherlands as well as worldwide, increasing numbers of persons took up running in the last three decades. Running is a feasible form of vigorous-intensity physical activity: it is not time-consuming and it can be done anywhere, at any time.

Although running has a positive effect on health and well-being, it also brings the possibility of sustaining a running-related injury (RRI). The number of runners sustaining an RRI is high, i.e. 30 to 79%.^{1,7} This wide range of incidence data is caused by differences in definition and assessment of RRI, type of runners followed (novice runners, recreational runners or elite runners), training load, period of follow-up and study design (prospective versus retrospective).^{1,7} Only two studies examined the incidence of novice runners and runners with limited running experience. In these studies the incidence of RRI was 12 and 33 per 1000 hours of running exposure during a follow-up of respectively 28 and 13 weeks.^{1,8}

Many intrinsic and extrinsic variables have been related to the development of RRI, including age, body weight, alignment, previous running and/or exercise experience, shoes, running terrain and psychological factors.^{9,10} Despite the numerous studies on risk factors for RRI, little consistency about the etiology of RRI was found. Van Mechelen¹¹ stated that only four factors were consistent related to RRI in recreational runners, i.e. previous injury, lack of running experience, running to compete and excessive weekly running distance.

Although runners with no or limited running experience are the ones most at risk of sustaining injury,¹² little information is available about the predictors for risk in this specific group. Therefore, the purpose of this study is to identify gender-specific predictors of RRI in novice runners training for a four-mile distance run.

Methods

Study design and Participants

The present study is part of a Randomized controlled trial of 532 novice runners training for a four-mile running event (GRONORUN study). The design of the

trial is presented in detail elsewhere.¹³ In the present study, the cohort of 532 novice runners was prospectively followed during a training program for a four-mile (6.7 km) distance run. Recruitment of participants for the study took place through advertisements in local media in May and June 2005. The training period started in the second week of July, 13 weeks before the four-mile running event, which took place in October 2005.

Healthy participants between 18 and 65 years of age, who had no injury of the lower extremity in the three months prior to inclusion and who had not been running on a regular basis in the previous twelve months, were eligible for inclusion in the study. Participants were excluded if there were absolute contraindications for vigorous physical activities according to the American College of Sports Medicine,¹⁴ or in case of unwillingness to keep a running log. Potential participants were sent written information about the study along with a baseline questionnaire and an invitation for a baseline interview and examination at the Center for Sports Medicine of University Medical Center Groningen (UMCG), the Netherlands.

The study design, procedures and informed consent process were approved by the Medical Ethics Committee (Number 2004/285) of UMCG. All participants provided written informed consent. Guidelines for reporting observational studies in epidemiology were followed according to the STROBE Statement.¹⁵

Baseline measurements

The baseline questionnaire was sent back by mail in a pre-paid envelope before the appointment for the baseline examination at the hospital. The questionnaire covered demographic variables, questions about history of previous musculoskeletal injury, previous participation in sports, conditions related to risk factors for cardiovascular diseases, motivation for engaging in a training program, and questions assessing type A/B behavior.

Information about previous musculoskeletal injury of the lower extremity and back were assessed per anatomical site. Open-ended questions were used to obtain self-reported data about body height (in cm) and body weight (in kg), which were then used to calculate BMI ($\text{weight (kg)/height}^2(\text{m})$).



Participation in sports was assessed by using open-ended questions concerning type of sport and estimated mean hours of sports participation per week. The various types of sports were categorized into axial loading (e.g. tennis and volleyball) and non-axial loading (e.g. swimming and cycling) sports. Further, a question on running experience in the past (“Have you ever participated in running on a regular basis?”) was used to assess the novelty to running.

The Jenkins Activity Survey (JAS) was used to determine type A/B behavior.¹⁶ Individuals with a pronounced type-A behavior, also referred to as coronary-prone behavior, may be more prone to injury. Type-A behavior is characterized by relatively high levels of achievement drive, aggressiveness, hostility, impatience, time urgency and competitiveness.¹⁶

During the baseline interview at UMCG an orthopedic assessment of the lower extremity was performed by a sports physician. Range of motion (ROM) of hip rotation (internal and external rotation) and dorsal flexion of the ankle were measured. A universal goniometer with arm length 30 cm from axis to tip was used to measure all ROMs with recordings in increments of 1.0°. Internal and external ROM of the hip was assessed with the participant supine and the tested hip and knee flexed to 90°. Ankle dorsal flexion was measured both with the knee fully extended and flexed to 90°. One arm of the goniometer was aligned with the fibular bone and the other with the plantar surface of the foot. Navicular drop was assessed by measuring the change in the height of the navicular tuberosity between sitting with the subtalar joint in neutral position and standing, weight-bearing with the subtalar joint in relaxed stance, as described by Brody.¹⁷ The navicular drop is a valid method to indicate level of foot pronation.¹⁸ Measurements were made twice for each foot, with results being averaged.

Assessment of RRI and running exposure

Self-reported information on RRI and running exposure was gathered using an internet-based running log. At the end of each training week, participants had to fill in the exposure time of running (in minutes) of the three training sessions. Per training session, participants also had to report running-related pain if present. Severity of pain was reported as: pain without running limitations, pain that caused a restriction in running, and running impossible because of an RRI. The anatomical

site of running-related pain was also reported. If a training session was canceled, the reason was asked for.

Definition of RRI

Definition of an RRI in this prospective cohort study is: running-related musculoskeletal pain of the lower extremity or back, causing a restriction of running for at least one week, that is, three scheduled consecutive training sessions.

Training program

All participants received standardized written and oral information on intensity of running and on warming up and cooling down. Each training week, except the last week — that is, the week of the four-mile run — consisted of three training sessions represented by a combination of running and walking. Participants were encouraged to run on Monday, Wednesday and Saturday, and were advised to run at a comfortable pace at which they could converse without losing breath. All participants trained individually, without a trainer, on a self-chosen course. Participants were randomized into an 8-week training program or a 13-week training program for novice runners. The exact content of the training program was published elsewhere.¹³ No differences were seen between incidence of RRI in the two training groups,⁸ thus both groups were considered as one in this analysis.

Statistics

Demographic variables and potential predictors of RRI were analyzed for differences between male and female participants at baseline using 2-tailed t-tests for normally distributed continuous variables. Chi-square statistics were used for discrete variables. Differences were considered statistically significant at $p < 0.05$. Incidence of RRI was calculated for all participants and for men and women separately as the number of new injuries reported per 1000 hours of running exposure. Since participants had different training programs the primary outcome was exposure time until the first RRI. Exposure time (in hours of running exposure) was calculated from the time a participant started the running program until he reported an RRI (injured runners) or until the end of the program (non-injured runners).



Potential predictors of RRI were first univariately analyzed to observe the independent link with RRI. Variables independently associated ($p \leq 0.25$) with RRI among either men or women were entered into gender-specific multivariate Cox regression prediction models. Hazard Ratios (HR) and the corresponding 95% CI were calculated for the factors associated with RRI. The weight for each risk factor was adjusted for other risk factors. The final score was a hazard ratio for risk of RRI compared to participants without RRI identified in the model. All analyses were performed using SPSS version 14.0 (SPSS Inc, Chicago).

Funding

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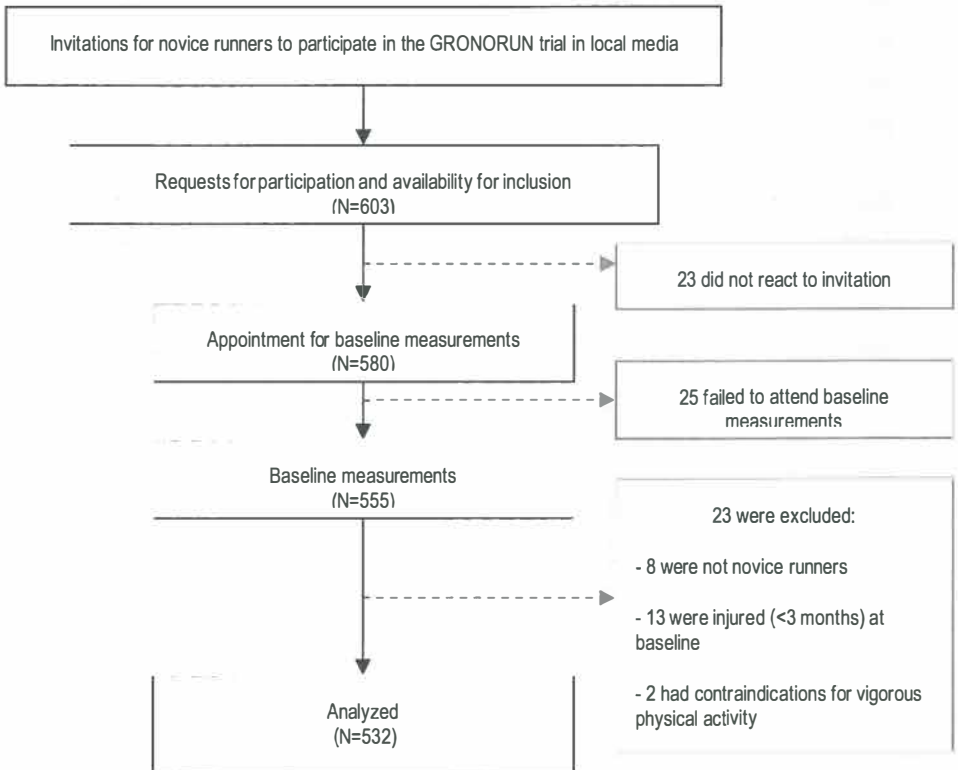


Figure 6.1: Participants Flow

Results

Participants

A total of 603 participants were available for inclusion in the GRONORUN study. The flow of participants is shown in Figure 6.1. Forty-eight (8.0% of 603) did not react to the invitation or failed to attend the hospital for the baseline assessment. Among those participants who attended the baseline assessment, 23 of 555 (4.1%) were excluded because they did not meet the study eligibility criteria. A total of 532 novice runners were included in the study. Of all included participants, 46 (8.6%) did not start running during the follow-up period. Since the Cox regression prediction models take exposure into account, all 532 participants were analyzed.

Descriptive data

The baseline characteristics of male and female participants are shown in Table 6.1. Of the 532 analyzed participants, 306 (57.5%) were female. Forty-seven percent of all analyzed participants had never run on a regular basis before. Male participants were significantly older (42 versus 38 years of age, $p < .01$) and had a significantly higher BMI (26 versus 24, $p < .01$) than female participants. Further, female participants had higher internal and external rotation ROM of the hip.

Outcome data

A total of 100 RRIs were reported by 486 runners at risk. The incidence of RRI per 1000 hours of exposure was 33 (95% CI 27-40). The number of injured runners was 20.6 per 100 runners at risk. The total exposure time of running was 385 (sd=226) minutes in male and 381 (sd=198) minutes in female participants during the training program.



Table 6.1: Baseline Characteristics of Participants (mean, sd)

Characteristic	Dimension/Qualifier	Men = 226 (42.5%)	Women = 306 (57.5%)
Age **	Years	42.3 (9.9)	37.9 (9.9)
BMI **	kg · m ²	25.9 (3.3)	24.2 (3.4)
Running experience **	No	91 (43.3%)	159 (52.0%)
	Yes	135 (59.7%)	147 (48.0%)
Previous injury	No	109 (48.2%)	149 (48.7%)
	> 3 ≤ 12 months	53 (23.5%)	82 (26.8%)
	> 12 months	64 (28.3%)	75 (24.5%)
Sports activities *	No	117 (51.8%)	132 (43.1%)
	With axial load	67 (29.6%)	82 (26.8%)
	Without axial load	42 (18.6%)	92 (30.1%)
Type A/B behavior	Extreme Type A	59 (26.2%)	109 (35.9%)
	Type A	47 (20.9%)	65 (21.4%)
	Type B	42 (18.7%)	63 (20.7%)
	Extreme type B	77 (34.2%)	67 (22.0%)
Hip internal rotation	Degrees left **	30.6 (8.1)	35.9 (9.5)
	Degrees right **	31.1 (8.8)	37.7 (8.3)
Hip external rotation	Degrees left **	39.7 (11.6)	45.7 (14.3)
	Degrees right **	40.2 (12.9)	45.8 (13.9)
Ankle dorsal flexion (flexed knee)	Degrees left	104.7 (7.8)	103.6 (11.5)
	Degrees right	104.6 (7.5)	103.8 (8.7)
Ankle dorsal flexion (extended knee)	Degrees left	99.2 (8.2)	99.0 (10.9)
	Degrees right	99.2 (7.8)	99.1 (9.2)
Navicular drop	Millimeters left *	6.6 (3.5)	6.0 (3.1)
	Millimeters right	6.7 (3.5)	6.2 (2.8)

* Difference between men and women, p<0.05
 ** Difference between men and women, p<0.01

Main results

Of all predictor variables for RRI assessed at baseline, (male) gender, BMI, previous lower extremity injury, type of sports activities and internal hip rotation were univariately associated ($p < .25$) with RRI in all participants. In male participants BMI, previous lower extremity injury, type of sports activities and

type-A behavior were univariately associated ($p < .25$) with RRI. In female participants age, internal rotation of the hip and the navicular drop were univariately associated ($p < .25$) with RRI.

We found that there were different predictors for RRI in male and female novice runners. The multivariate Cox regression model for male participants showed that higher BMI per unit (HR 1.15; 95% CI 1.05–1.26), history of previous injury (HR 2.7; 95% CI 1.36–5.55) and type of previous sports activities (HR 2.05; 95% CI 1.03–4.11) were significantly ($p < .05$) associated with RRI. In female participants only the navicular drop remained in the multivariate Cox regression model as a significant predictor for RRI.

Table 6.2: Unadjusted Cox regression models for male and female participants

Predictor variable	Dimension/Qualifier	Men		Women	
		HR	p	HR	p
Gender	<i>Female is reference</i>	1.5	.04	1.0	
Age	<i>10 Years</i>	.90	.44	.83	.24
BMI	<i>1 kg · m⁻² increase</i>	1.12	.01	.99	.84
Running experience	<i>No</i>	1.08	.78	1.16	.62
	<i>Yes</i>	1.0		1.0	
Previous injury	<i>No</i>	1.0		1.0	
	<i>> 3 ≤ 12 months</i>	1.90	.05	.88	.74
	<i>> 12 months</i>	1.48	.25	1.45	.27
Sports activities	<i>With axial load</i>	1.0		1.0	
	<i>Without axial load</i>	1.49	.24	1.41	.35
	<i>No</i>	1.13	.76	1.16	.71
Type A/B behavior	<i>Sum score Jenkins</i>	1.02	.08	1.0	.96
Hip internal rotation	<i>Degrees</i>	1.00	.63	.98	.08
Hip external rotation	<i>Degrees</i>	1.01	.28	1.00	.86
Ankle dorsal flexion (flexed knee)	<i>Degrees</i>	1.01	.42	1.00	.61
Ankle dorsal flexion (extended)	<i>Degrees</i>	1.01	.45	1.00	.87
Navicular drop	<i>Millimeters</i>	1.02	.40	.92	.01



Table 6.3: Final adjusted Cox regression models for male and female participants

Predictor variable	Dimension/Qualifier	Men		Women	
		HR	95%CI	HR	95%CI
Age	10 Years	–	–	0.84	0.62-1.13
BMI	kg · m ⁻²	1.14	1.05-1.25	–	–
Previous injury	No	1.0		–	–
	> 3 ≤ 12 months	2.64	1.32-5.30		
	> 12 months	2.14	1.05-4.35		
Sports activities	With axial load	1.0		–	–
	Without axial load	2.02	1.00-4.05		
	No	1.23	0.54-2.78		
Type A/B behavior	Sum score Jenkins	1.02	0.99-1.04	–	–
Hip internal rotation		–	–	0.99	0.97-1.01
Navicular drop		–	–	0.87	0.77-0.98

Discussion

The purpose of this prospective cohort study was to detect gender-specific predictive factors for RRI in a group of novice runners. We found that BMI, history of previous musculoskeletal injury of lower limb or back, and participating in sports without axial loading prior to the program were significant predictors for RRI in male participants starting a training program for novice runners. In female participants navicular drop was the only significant predictor for RRI. The results indicate that predictors for RRI are different in male and female novice runners. This finding is in line with results found by other authors who also concluded that male and female runners have different risk profiles.^{4,19}

Previous injury is one of the predictors that is consistently associated with RRI.^{4,5,7,20} The hazard of RRI during the follow-up for men who had suffered a previous lower limb injury prior to the beginning of our study was 2.6 times that of men who had not suffered such injury. The link between previous injury and RRI during the follow-up was only found in male participants. The strength of the association found in our study is comparable to the association reported by Macera et al.,⁴ who found an odds ratio for injury of 2.7 in habitual runners with previous

injury in the past year. Additionally, in a study among marathon runners with a history of previous injury in the 12 months prior to a road race, the odds ratio of a subsequent injury in the months after the race was 6.3 in male participants and 7.6 in female participants.²⁰

It is unclear whether the term “previous injury” as often used in literature is an RRI or a sports injury in general. A previous RRI could negatively influence the susceptibility of a new RRI more than a previous sports injury, but this has not been investigated. The lack of association between previous injury and RRI in the female novice runners may be explained by the observable fact that the majority of the female participants had never ran on a regular basis before, whereas a significantly higher percentage of male participants had run on a regular basis previously.

Male novice runners participating in sports activities without axial loading at baseline (such as cycling and swimming) were 2.1 times at a higher risk (95% CI 1.0 to 4.1) of sustaining an injury than males participating in sports activities with axial load at baseline (sports involving running and jumping). The effect of participation or non-participation in sports activities before starting with running has been investigated only in military populations.²¹ Studies conducted on the general population did not find clear links between participation in other sports activities and development of RRI.^{5,7} The difference between our results and those from other studies could be due to our categorizing “previous sports activities” into axial and non-axial loading. Persons who engage in sports activities like swimming and cycling are more likely to have a high cardiorespiratory endurance compared to inactive persons or those engaging in axial loading activities with an interval component. It may be that these persons with higher cardiorespiratory endurance trained more intensively compared to the ones with lower cardiorespiratory endurance, while the musculoskeletal system had not adapted well enough to resist the repetitive forces of running. In this light, persons engaging in sports with axial loading at baseline are more used to axial loading and therefore less prone to sustain an RRI when they start running.

Higher BMI is associated with increased risk of sustaining an RRI among male participants. The Hazard Ratio was 1.14 (95% CI 1.1 to 1.3) per unit of BMI increase. Runners with higher BMI may have a higher risk of RRI due to the added physical stress of additional weight.²² There was no association between BMI and



RRI in the female novice runners. We did not measure running speed, but the lack of association could be explained by an altering, i.e. decrease, of running speed in female runners with higher BMI. This phenomenon of naturally decreasing training load by a decrease of running speed is also seen in older runners. The biomechanics of running is different in older than younger runners, indicating a loss of shock-absorbing capacity in the older runners.²³ The increase of susceptibility to RRI is compensated by altering running speed. In the current study, age was not a predictor for RRI. Another prospective cohort study with a follow-up of six months also reported a similar average age in the injured and non-injured groups of male runners.⁶ In a study on recreationally active adults an association between older age and lower risk of injury was found.¹⁹ The dissimilarity in findings with our study may be explained by a “healthy runner effect”, since the participants in the study of Hootman et al.¹⁹ were already participating in running, jogging and walking.

Navicular drop as a composite measure of excessive pronation is a clinical measure used to quantify motion occurring at the subtalar joint. A navicular drop greater than approximately 10 mm should be considered abnormal.¹⁸ We found that female participants with higher values of navicular drop were more prone to RRI. This finding is supported by Bennett et al.,²⁴ who report that female high school cross-country athletes with greater foot pronation as measured by navicular drop had an increased risk of developing medial tibial stress syndrome (MTSS).

In a study conducted by Reinking et al.,²⁵ proportions of those below and above a 10-mm navicular drop were not different between injured and non-injured participants. There was no association between navicular drop and RRI in male novice runners, therefore the exact link between navicular drop and RRI has yet to be determined.

The behavioral pattern known as “type A” is frequently mentioned as a psychological factor associated with competitive urge.¹⁰ The score on the Jenkins Activity Survey indicating type-A behavior was not related to the hazard of sustaining an injury among male or female participants in the current study. The theory of having an above-average competitiveness leading to suppression of feelings of fatigue and exertion and eventually leading to an overuse injury was not supported.

Lack of ROM may lead to increased stress on the adjacent joints and an ensuing overuse injury.²⁶ This hypothesis was not supported by the data. Measurements of internal and external rotation of the hip and dorsal flexion of the ankle were not found to be related to RRI in novice runners. This finding was also seen in a prospective cohort study of recreational runners and military recruits.^{2,27}

Previous running experience in this study was not associated with RRI. Macera et al.⁴ suggested that both new and seasoned runners were at greater risk for injury. Since participants were all novice runners starting with a training program for beginners, previous running experience was categorized as “had never ran on a regular basis before” and “ran on a regular basis before, but not in the twelve months before baseline measurements”. Therefore, all participants were runners who were not adapted to the applied stress caused by running. Most of the studies on RRI reporting an association between running experience and RRI did measure running experience in terms of number of years.^{4,5,28} Hence the difference in outcome could be explained by discrepancy of the definition of running experience.

Our results should be interpreted with caution because of several study limitations. First, not all predictors for RRI were available in this cohort study. Many other variables can affect the development of running-related injuries. Accounting for all of these variables is extremely difficult though. We have chosen to select those factors that can be assessed easily by a general practitioner and other clinicians. Second, the accuracy of self-reported exposure might be of concern. There could have been an overestimation or underestimation of exposure time. The same applies to the self-reported RRI, since variability in pain perception exists among individuals: one individual with an RRI may have continued to participate, whereas a second individual with the same injury may have interrupted participation for days or weeks.

Conclusion

Male and female novice runners have different risk profiles. Higher BMI, previous injury, and previous sports participation without axial loading are important predictors for RRI in male participants. Further research is needed to detect more predictors for female novice runners. Clinicians may use this information to appropriately inform novice runners of the risk of an RRI when starting to run.



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Chapter 7

General Discussion

The scope of this thesis was to study injuries in recreational runners. The main purpose of this thesis was to determine the effect of a graded training program on the number of injuries in novice runners. The second purpose was to determine modifiable and non-modifiable risk factors for running related injuries in novice and recreational runners. In this general discussion the results of the research described in the previous chapters of this thesis are discussed in a broader perspective. The main conclusions will be summarised, followed by a reflection on the methodological considerations concerning the results of this thesis. Finally, recommendations for future research are described.

Incidence

In chapter 3 (pilot study) the incidence of RRI was studied in a mixed group of 629 both recreational and novice runners. The results showed an incidence of 28 and 35 injuries per 1000 hours of running in respectively female and male participants during the eight-week training program. In the Gronorun Study (chapter 5) the incidence numbers were 30/1000 hours in the graded training program (13 weeks) and 38/1000 hours in the standard training program (8 weeks). Only a few other studies on RRIs have assessed exposure time in a way that the incidence per 1000 hours of exposure to running could be calculated. Bovens et al.¹ found an injury incidence of 12/1000 hours. Although the definitions of RRI were the same as the Gronorun Study, the duration of follow-up and the ultimate goal of training (training for a marathon versus a four-mile race) were different. In another prospective cohort study² 153 recreational runners, running more than 20 km per week at baseline, were observed for six months during their usual training routines. In this study the incidence was 59/1000 hours of exposure. This relatively high incidence may be due to the high rate of participants that were lost to follow-up. Of initially 153 participants only 87 runners were included in the analyses. It is plausible that injured participants had more affinity with research on the topic of running related injuries compared to their healthy co runners, and therefore affecting the incidence outcome.

The 'Vancouver Sun Run' (VSR) study³ showed several similarities with the pilot study as described in this thesis. The 13 week VSR training protocol was designed to accommodate novice and intermediate runners. The VSR training programme required the participants to run three times a week; also two of these sessions were



separated from the group run on the day of their respective clinic. However, no exposure data were obtained, and therefore assessment of injury incidence (per 1000 hours of exposure) was not possible. Overall, 29.5% of the runners surveyed in the 13 week VSR training programme experienced an injury defined as pain during or after running. In our pilot study (chapter 3) the injury rate was 23.2% in female and 25.9% in male participants during the 8-week follow-up. The overall injury rates in the Gronorun Study were 20.8% in the graded- and 20.3% in the standard training program group. In the study of Bovens et al.¹ 58% of the runners training for a 15-km run sustained a running related injury during a period of 28 weeks. The prospective cohort studies described in this thesis (chapter 3 and 5) have shorter follow-up periods with less time at risk, therefore the lower number of RRIs per 100 runners at risk may be understandable.

It can be concluded that the injury incidences expressed as the number of RRI per 1000 hours of exposure and per 100 runners at risk that were found in both the pilot study as well as the Gronorun Study are in line with incidence numbers found in other studies on recreational and novice runners.¹⁻³

Risk factors

Both chapters 3 and chapter 5 focused on gender specific risk factors for RRI. Chapter 3 describes the study on risk factors for RRI in a mixed group of recreational runners who were training for a four-mile (6.7 km) recreational running event in an eight-week period. In the intervention study described in chapter 5 no differences were found between the intervention group (13-week training program) and the control group (8-week training program). For this reason it was decided to combine the data of both the intervention and the control group to one set, and to consider the two training groups as one cohort of novice runners. This study on risk factors for novice runners is presented in chapter 6.

Running experience, type of previous sports activity, and higher Body Mass Index (BMI) were associated with RRI in both male and female runners. The variables age and previous injury were only associated with RRI in male runners, whereas lower levels of navicular drop were associated with RRI in female runners. Below, a description is given of possible mechanisms explaining the associations.

In chapter 3 the results showed that both male and female participants without any running experience were the most at risk sustaining a RRI during the four mile training program. Having no running experience was the strongest predictor for RRI, whereas in the Gronorun Study (chapter 6) no association was seen between previous running experience (> 1 year ago) as a protective factor and RRI. These findings indicate that physical adaptation of running may be more important than running experiences in the past. Review articles of van Mechelen⁴ and Hoerberigs⁵ also stated that no experience in running is a major risk factor for sustaining an RRI. Although they arrived at the same conclusion, running experience was defined differently, that is, as the number of years engaged in running, and the runners that were studied were having more running experience.

In chapter 3, female runners who reported engaging in non-axial sports activities (swimming cycling) at baseline were almost two times more at risk of sustaining an RRI compared to females who were engaging in types of sports like volleyball and tennis. The effect of type of previous activity was also seen in chapter 6 in male novice runners. On the one hand, it is to be expected that the endurance capacity of participants who were previously active in non axial sports is sufficient, and possibly they had higher self selected running pace, compared to the previously inactive participants. On the other hand the musculoskeletal system was not adapted to repetitive axial loadings. Combining these two aspects may explain the higher susceptibility of injury in participants who were previously engaged in non-axial loading sports activities.

Higher BMI was associated with higher risk of injury in male novice runners, and in female recreational runners. In daily practice it is often discussed whether persons with higher BMI should choose running as a form of physical exercise. Some argue that heavier persons may have a higher risk of RRI due to the added physical stress of extra weight.^{6,7}

As presented in this thesis, the significant effect of BMI on risk of injury was not seen in female novice, and male recreational runners. Therefore, it is also conceivable that runners with higher BMI run at a slower pace, i.e., running less distance, in order to reduce the training load. In the prospective studies that have been described in this thesis only exposure time without information on distance was assessed, and therefore no conclusions can be drawn about the correlation between BMI and running pace. This phenomenon of naturally decreasing training



load by a decrease of running speed has been found in older runners.⁸ The biomechanics of running is different in older compared to younger runners, indicating a loss of shock-absorbing capacity in the older runners.⁸ The increased risk for a RRI is thought to be compensated by altering running speed.

Until now, previous injury is one of the predictors that is consistently associated with RRI.^{6,9,11} The results of chapter 3 and 6 show different associations between previous injury and RRI. In the Gronorun Study (chapter 6) a higher risk of injury was seen only in male novice runners. The hazard of RRI during the follow-up for male Gronorun runners who had suffered a previous lower limb injury was 2.6 times compared to that of men who had not suffered such injury. According to Taunton et al.,³ of those with a previous injury 42% indicated not being completely rehabilitated before starting with the training program. As Hootman¹² stated that 'previous lower extremity injuries that were completely healed should not increase the risk for a subsequent lower extremity injury', and since one of the exclusion criteria of the Gronorun Study was "having sustained an injury of lower limb in the three months prior to the program" an incomplete healing of a previous injury is unlikely to explain the effect.

In chapter 6, one of the anatomical measurements that was taken was the navicular drop, as a composite measure of excessive pronation. It is a clinical measure used to quantify motion occurring at the subtalar joint.¹³ In female participants a higher score of navicular drop was associated with higher risk of RRI. This finding is supported by Bennett et al.,¹⁴ who reported that female high school cross-country athletes with greater foot pronation as measured by navicular drop had an increased risk of developing medial tibial stress syndrome (MTSS). The exact relations of navicular drop, excessive pronation and RRI have to be further clarified and confirmed in future research.

Prevention of injuries in novice runners

The focus in the literature is primary on understanding the factors that contribute to the risk of a running related injury. There has been less emphasis in the literature on developing training programs that are suitable for novice runners. In running stores, running magazines, and on the internet many so-called "training programs for novice runners" designed by trainers or sports physicians can be found.

However, none of the available programs have been tested in the running population. With the Gronorun trial, a first step has been taken into the prevention of injuries in novice runners. The Gronorun trial was designed to see whether a training program that progresses more slowly, a 13-week versus an 8-week training program, will result in fewer injuries. Our results, however, showed no significant effect of the adapted training program on the incidence of RRI in novice runners. As discussed in chapter 5, possible explanations for the ineffectiveness of the graded training program can be related to the dose-response relationship. The contrast of training load per week in the 8-week and 13-week training program may have been too small to cause and register an effect. Other aspects of the Gronorun trial that may have been the cause of the lacking of an effect are (equal) training frequency and starting point. Both training programs consisted of three training sessions per week. Consequently, there were only one or two days of rest between two training sessions. For novice runners, two days of rest may be too short for the musculoskeletal tissue to adapt to running. The 8- and 13-week training program both started with a total time of 30 minutes of running. It is plausible that 30 minutes of running is too much for novice runners to start with. Maybe novice runners, especially the ones who are not used to receive repetitive axial loadings, should be advised to walk briskly for 30 minutes before they start with a running program.

Study limitations

In the pilot study (chapter 3) as well as the Gronorun Study (chapter 5 and 6) the primary outcome was a self-reported running related injury. Although there was a free outpatient clinic for all Gronorun participants, only few of the injured runners did attend the clinic. Therefore no information was reported on specific diagnoses of injuries. As running is primarily an unorganized sport it was not possible to measure exposure time. Participants registered their exposure time in a paper running log (pilot study) or in a digital running log (Gronorun Study). The accuracy of the self-reported compliance is unknown. Also, the follow-up period in both prospective studies was relatively short. Therefore, it could have been that the incidence of RRI was underestimated, since most of the RRIs are overuse injuries and can present on longer term.



In the Gronorun trial the volume of training was not equal in both groups. Thus, if the total volume of training is a risk factor, then the two groups were not equally exposed to that risk factor. To overcome the aspect of unequal volume of training the primary outcome should have been turned into the number of injuries per 1000 hours of exposure. However, it takes a massive number of participants to identify such an effect.

Future research

First of all, there is a need for evidence-based information on how to prevent injuries in novice and recreational runners. Future prospective studies should determine whether modifications of training programs will make a difference in ultimate injury rates. Secondly, more information is needed on risk factors for RRI in novice and recreational runners. Until recently, running was mainly a competitive sport.¹⁵ Therefore, studies that have formed the basis of the literature on running related injuries have been primarily observational studies using volunteer samples of runners obtained from lists or from road races. Modifiable risk factors may be targeted by specific training methods (like a preconditioning program) and non-modifiable factors (like running experience) can be used to target intervention measures to those athletes who are at an increased risk.

Before the incidence, risk factors, and preventive intervention of RRI are further studied, consensus agreements on definitions and measurements are needed. There still is a lack of consistency in definition of the primary outcome (RRI) as well as in the methods of measuring potential risk factors for RRI. Therefore it is extremely difficult to synthesise results from different studies. In reaching the consensus one must keep in mind the practicability of a measurement.

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Summary

Summary

Although running is a popular form of recreational exercise that is beneficial for fitness and health, injuries are a significant side effect. Reported rates of running-related injuries are high, and vary from 30 to 79%.

In **Chapter 2**, an overview is given of current concepts in running-related injuries. The incidence of injuries among runners is high and varies between 2.5 and 38 per 1000 hours of running. The diversity of incidence strongly depends on study population, definition and assessment of injury, and period of follow-up. The literature on the aetiology of injuries in novice runners is scarce. Although there is much literature concerning running-related injuries in other populations than in novice runners, there is little agreement when it comes to the aetiology of these injuries. Risk factors that are consistently associated with the occurrence of injuries in runners are higher running mileage and previous injury. There is a lack of proof for the link between gender, age, anatomical variation and biomechanical variables, psychological factors and running-related injuries. Many different methods to prevent injuries are currently being recommended and practiced by runners. However, to date no preventive interventions have been tested in the population of recreational and novice runners for their preventive capabilities.

A pilot study was conducted to gain more insight into the incidence and risk factors for injuries in recreational runners. **Chapter 3** describes this pilot study, in which recreational runners were followed during an eight-week training period preparing for the 4-mijl van Groningen (Groningen 4-mile run) event. Several potential risk factors were prospectively measured in 629 novice and recreational runners. They were observed for any running-related musculoskeletal injuries of the lower limbs and back. A running-related injury was defined as any musculoskeletal pain of the lower limb or back causing a restriction of running for at least one day. At least one RRI was reported by 25.9% of the runners during the eight-week observation period. The incidence of RRI was 30.1 (95% confidence interval (CI) 25.4–34.7) per 1,000 hours of running exposure. Multivariate Cox regression showed that male participants were more prone to sustain a running-related injury than female participants (HR 1.4; 95% CI 1.0–2.0). No prior running experience was the most important risk factor in male (HR 2.6; 95% CI 1.2–5.5) and female (HR 2.1; 95% CI 1.2–3.7) participants. The results showed that the incidence of running-related



injuries in recreational runners preparing for a four-mile running event is substantially high. Male and female participants have different risk profiles. Furthermore, the findings suggest that novice runners are the most availed by preventive interventions for RRI. For that reason a preventive intervention – a graded training program applying the 10 Percent Rule – was developed to decrease the incidence of running-related injuries among novice runners. An increase of no more than 10% per week is suggested to prevent the occurrence of a running-related injury.

The design of the randomised controlled trial (i.e. the Gronorun study) testing the effect of this intervention is presented in **Chapter 4**. The GRONORUN study (Groningen Novice Running) is a 2-armed randomized controlled trial comparing a standard 8-week training program (control group) and an adapted, graded, 13-week training program (intervention group), on the risk of sustaining an RRI. Participants were novice runners (N = 532) preparing for a recreational 4-mile (6.7-km) running event. The graded 13-week training program was based on the 10% training rule. Both groups registered information on running characteristics and RRI using an Internet-based running log. The primary outcome measure was RRIs per 100 participants. An RRI was defined as any musculoskeletal complaint of the lower extremity or back causing a restriction of running for at least 1 week.

Chapter 5 presents the main outcome of this Gronorun study, that is, the effectiveness of a graded training program on the number of running-related injuries among novice runners. The graded training program was not preventive for sustaining an RRI ($\chi^2 = 0.016$, $df = 1$, $P = .90$). The incidence of RRI was 20.8% in the graded training program group and 20.3% in the standard training program group. The Gronorun trial showed no effect of a graded training program (13 weeks) in novice runners, applying the 10% rule, on the incidence of RRI compared with a standard 8-week training program.

Chapter 6 reports on the predictors of running-related injuries among male and female novice runners following a beginners' training program. Participants of the Gronorun trial (226 men, 306 women) were prospectively followed during the training period. After completing a baseline questionnaire and undergoing an orthopedic examination, they were observed for a period of thirteen weeks maximal. An RRI was defined as any self-reported running-related musculoskeletal

pain of the lower extremity or back, causing a restriction of running for at least one week. Twenty-one percent of the novice runners had at least one RRI during follow-up. The multivariate adjusted Cox regression model for male participants showed that BMI per $\text{kg} \cdot \text{m}^{-2}$ (HR 1.15; 95% CI 1.05–1.26), previous injury in the past year (HR 2.7; 95% CI 1.36–5.55) and previous participation in sports without axial load (HR 2.05; 95% CI 1.03–4.11) were associated with RRI. In female participants only navicular drop (HR 0.85; 95% CI 0.75–0.97) remained a significant predictor for RRI in the multivariate Cox regression modeling. Type-A behavior and range of motion (ROM) of the hip and ankle did not affect risk. The results showed that male and female novice runners have different risk profiles.

Chapter 7 contains the general discussion. It stipulates that the follow-up period in both the pilot study as well as the Gronorun study was relatively short. Therefore the incidence of RRI might have been underestimated. Finally, recommendations for practice and future research are described. Consensus agreements on definitions of RRI and measurements of potential risk factors are needed. Future prospective studies should determine whether modifications of training programs will make a difference in ultimate injury rates in novice and recreational runners.



Samenvatting

Hoewel hardlopen een populaire vorm van sportief bewegen is en een positief effect heeft op de gezondheid, zijn de hardlooplessures een significante bijkomstigheid. Uit verschillende onderzoeken blijkt dat het aantal geblesseerde lopers groot is en varieert van 30 tot 79%.

In **Hoofdstuk 2** wordt een overzicht gegeven van huidige concepten die gelden voor hardlooplessures. De incidentie van blessures onder hardlopers is hoog en varieert tussen 2.5 en 38 per 1000 uren hardlopen. De diversiteit van incidentiegetallen hangt sterk af van studiepopulatie, definitie en beoordeling van blessure en duur van de studiekeerode. De literatuur over de etiologie van blessures bij beginnende hardlopers is schaars. Hoewel er veel literatuur beschikbaar is over hardlooplessures bij andere populaties dan beginnende lopers, is er weinig overeenstemming wanneer het over de etiologie van deze blessures gaat. De risicofactoren die consequent met het voorkomen van hardlooplessures worden geassocieerd zijn grotere loopafstanden afstand en blessureverleden. Er is een gebrek aan bewijs voor een verband tussen hardlooplessures en geslacht, leeftijd, anatomische en biomechanische kenmerken en psychologische kenmerken. Er zijn verschillende methodes die geadviseerd en uitgevoerd worden door de hardlopers met het oog op de preventie van hardlooplessures. Tot op heden zijn er geen preventieve maatregelen onderzocht in een populatie van recreatieve en beginnende hardlopers.

Een pilot studie werd uitgevoerd om meer inzicht in de incidentie en risicofactoren van blessures in recreatieve hardlopers. **Hoofdstuk 3** beschrijft deze studie waarin 629 recreatieve hardlopers gevolgd werden tijdens een trainingsperiode van acht weken in voorbereiding op de 4 mijl van Groningen. Verscheidene potentiële risicofactoren werden voorafgaande aan de trainingsperiode in kaart gebracht. Tijdens de trainingsperiode werd gekeken of de deelnemers een hardloop gerelateerde blessure hadden. Een hardloop gerelateerde blessure werd gedefinieerd als pijn aan de onderste extremititeit of rug welke werd veroorzaakt door hardlopen en een beperking van het hardlopen van tenminste één dag tot gevolg had. Door 25.9% van de deelnemers aan het onderzoek werd tenminste één hardlooplessure gemeld. De incidentie van hardlooplessures was 30.1 (95%

betrouwbaarheidsinterval [BI] 25.4-34.7) per 1.000 uren hardlopen. Multivariate Cox regressie analyse toonde aan dat de mannelijke deelnemers iets meer kans hadden op een hardlooplessure dan vrouwelijke deelnemers (HR 1.4; 95% BI 1.0-2.0). Wanneer men niet eerder had hardgelopen, was de kans om geblesseerd te raken het grootst bij zowel mannen (HR 2.6; 95% BI 1.2-5.5) als bij vrouwen (HR 2.1; 95% BI 1.2-3.7). De resultaten toonden aan dat de incidentie van hardlooplessures bij recreatieve hardlopers die trainen voor de 4 mijl van Groningen wezenlijk hoog is. Het blijkt dat mannelijke en vrouwelijke deelnemers verschillende risicoprofielen hebben. Uit de bevindingen lijkt naar voren te komen dat de beginnende hardloper de meeste baat zouden kunnen hebben bij een preventieve maatregel. Om die reden werd een preventieve interventie – een trainingsprogramma met een langzamere opbouw – ontwikkeld. Van een verhoging van niet meer dan 10% per week wordt verwacht dat het beschermt tegen hardlooplessures.

Het ontwerp van de gerandomiseerde studie (de Gronorun studie) waarin het effect van deze interventie wordt getest is beschreven in **Hoofdstuk 4**. De GRONORUN studie (het Groningen beginners hardlooplesonderzoek) is een gerandomiseerde studie waarin de blessurekans van een standaard trainingsprogramma van 8 weken (controlegroep) en een aangepast, langzamer oplopend, 13 weken trainingsprogramma (interventiegroep), met elkaar werden vergeleken. De deelnemers waren beginnende hardlopers (N = 532) die trainden voor een recreatieve 4 mijl (6.7km) hardlooplewedstrijd. Het trainingsprogramma van 13 weken (interventie) was gebaseerd op de 10% regel. Beide groepen registreerden informatie over het hardlopen en eventuele opgelopen blessures via een digitaal logboek. De primaire uitkomstmaat was het aantal hardlooplegerelateerde blessures per 100 deelnemers. Een hardlooplegerelateerde blessure werd gedefinieerd als een blessure aan onderste extremiteit of rug welke veroorzaakt was door hardlopen en een beperking van hardlopen van minstens 1 week tot gevolg had.

In **Hoofdstuk 5** wordt het belangrijkste resultaat van de Gronorun studie gepresenteerd, d.w.z., het effect van het trainingsprogramma met een langzamere opbouw op het aantal blessures bij beginnende hardlopers. Het 13 weken durende trainingsprogramma zorgde niet voor een vermindering van het aantal blessures per 100 lopers. ($\chi^2 = 0.016$, $df = 1$, $P = .90$). De incidentie van hardlooplessures was



20.8% in de trainingsgroep met het 13-weken programma en 20.3% in de trainingsgroep met het standaard 8-weken programma. Het toepassen van de 10% regel had geen preventief effect op het ontstaan van hardloopleblessures bij beginnende hardlopers.

Hoofdstuk 6 beschrijft het onderzoek naar voorspellers van blessures bij mannelijke en vrouwelijke beginnende hardlopers. Voordat de deelnemers van de Gronorun studie (226 mannen en 306 vrouwen) aan het trainingsprogramma begonnen, werd een vragenlijst afgenomen en een orthopedisch onderzoek gedaan. Gedurende de follow-up van maximaal 13 weken werd een digitaal logboek bijgehouden waarin opgelopen blessures en het aantal minuten hardlopen geregistreerd. Eentwintig procent van de beginnende hardlopers had minstens één hardloopleblessure tijdens follow-up. Het multivariate Cox regressiemodel liet zien dat mannen met een hoger BMI (HR 1.15; 95% BI 1.05-1.26) een grotere kans hadden op een hardloopleblessure. Ook wanneer men een blessure heeft gehad in het afgelopen jaar (HR 2.7; 95% BI 1.36-5.55) en aan sport zonder axiale belasting deed (HR 2.05; 95% BI 1.03-4.11) was de kans op een hardloopleblessure groter. Bij de vrouwelijke deelnemers werd een verband gevonden tussen een lage waarde van de navicular drop (HR 0.85; 95% BI 0.75-0.97) en het krijgen van een blessure. Er werd geen verband gevonden tussen het ontstaan van een hardloopleblessure en gedragskenmerken en bewegingsuitslagen van de heup en enkel. De resultaten toonden aan dat de mannelijke en vrouwelijke beginnende hardlopers verschillende risicoprofielen hebben.

Hoofdstuk 7 bevat de algemene discussie. De vervolgperiode van zowel de pilot studie als de Gronorun studie was relatief kort. Daarom zou de incidentie van hardloopleblessures onderschat kunnen zijn. Tot slot worden de aanbevelingen voor praktijk en het toekomstige onderzoek beschreven. Voor het toekomstig onderzoek is het van belang dat er consensus wordt bereikt over de definitie van hardloopleblessures zodat verschillende studies eenvoudiger met elkaar vergeleken kunnen worden. Ook is er overeenstemming nodig in de methoden die worden toegepast bij het in kaart brengen van potentiële risicofactoren. Toekomstige prospectieve studies zouden moeten bepalen welke aanpassingen van trainingsprogramma's gedaan moeten worden om hardloopleblessures te voorkomen.



Dankwoord

Dankwoord

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