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No Effect of a Graded Training Program on the Number of Running-Related Injuries in Novice Runners

A Randomized Controlled Trial

Ida Buist,^{*†‡} MSc, Steef W. Bredeweg,^{†‡} MD, Willem van Mechelen,[§] MD, PhD, Koen A. P. M. Lemmink,^{†¶} PhD, Gert-Jan Pepping,^{†¶¶} PhD, and Ron L. Diercks,^{†‡} MD, PhD
From the [†]University Center for Sport, Exercise and Health, and [‡]Center for Sports Medicine, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands, [§]Department of Public and Occupational Health/EMGO Institute, VU University Medical Center, Amsterdam, The Netherlands, and [¶]Center for Human Movement Sciences, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands

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

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%,^{3,11-14,24,28} and from 7 to 59 RRIs per 1000 hours of running.^{3,11,12,19}

Most RRIs are overuse injuries of the lower extremity.⁸ The causes of these overuse RRIs are multifactorial.⁸ 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.²⁶ It is estimated that 60% of all RRIs can be attributed to training errors, that is, running too much too soon.⁸

Little research has been performed on the prevention of RRI in the running population. Several controlled studies on

*Address correspondence to Ida Buist, MSc, University Center for Sport, Exercise and Health, University Medical Center Groningen, University of Groningen, Hanzplein 1, 9700 RB Groningen, The Netherlands (e-mail: i.buist@sport.umcg.nl).

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the prevention of RRI exist.^{2,5,7,15,17,18,21-23,27} 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.²⁵ 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.¹⁰ 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.⁴ 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.¹⁶

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 Medicine,¹ 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 1).

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%.⁴ With a hypothesized 25% reduction of

TABLE 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

RRI in the graded training program group compared with the standard training program group, a total of 436 runners (2×218) were needed for a power of 80% and an alpha of 0.05.⁴ Assuming an attrition of 15% in the intervention period, a total of 512 (2×256) 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).

RESULTS

Randomization/Sample Attrition

The flow of participants is shown in Figure 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.

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 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 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 2A). Figure 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).

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 3.

The absolute number of RRIs per week in each training group is illustrated in Figure 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 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 4. The most frequently injured body parts were the lower leg (40%) and the knee (37%).

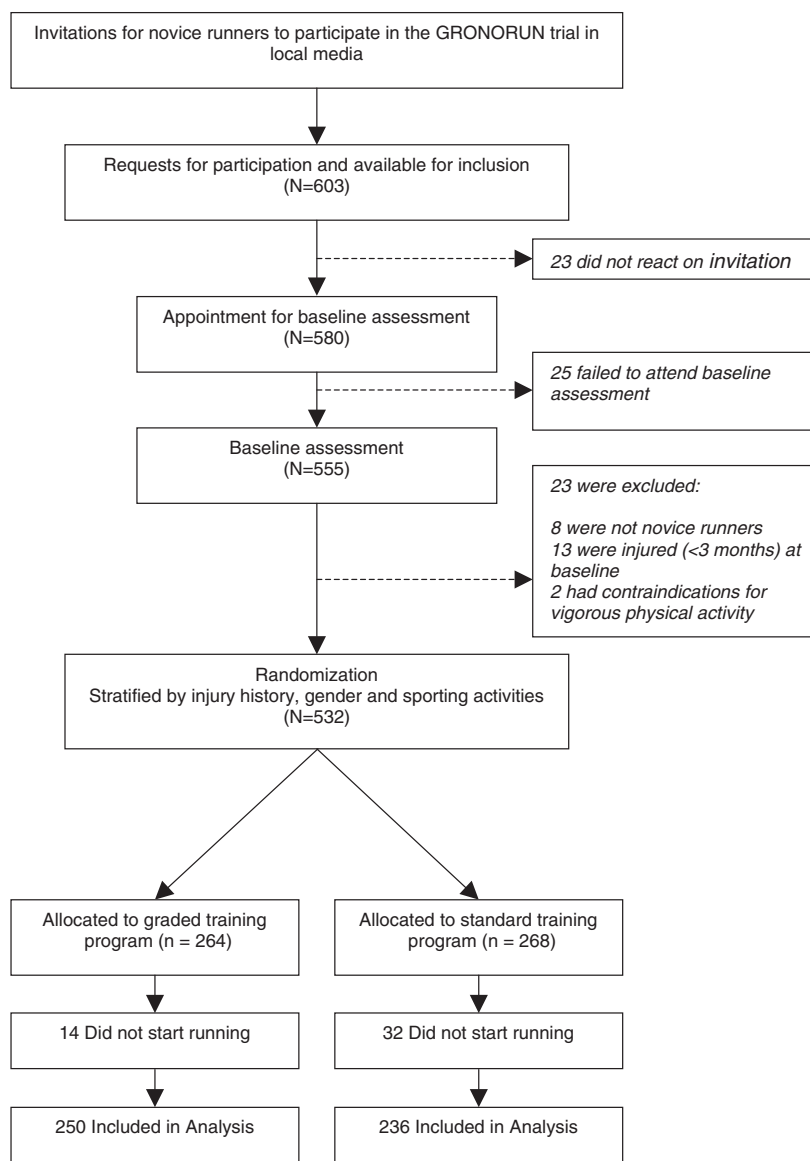


Figure 1. The flow of participants through each stage of the GRONORUN (Groningen Novice Running) trial.

TABLE 2
Baseline Characteristics of Participants in Graded Training Program and Standard Training Program Groups^a

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

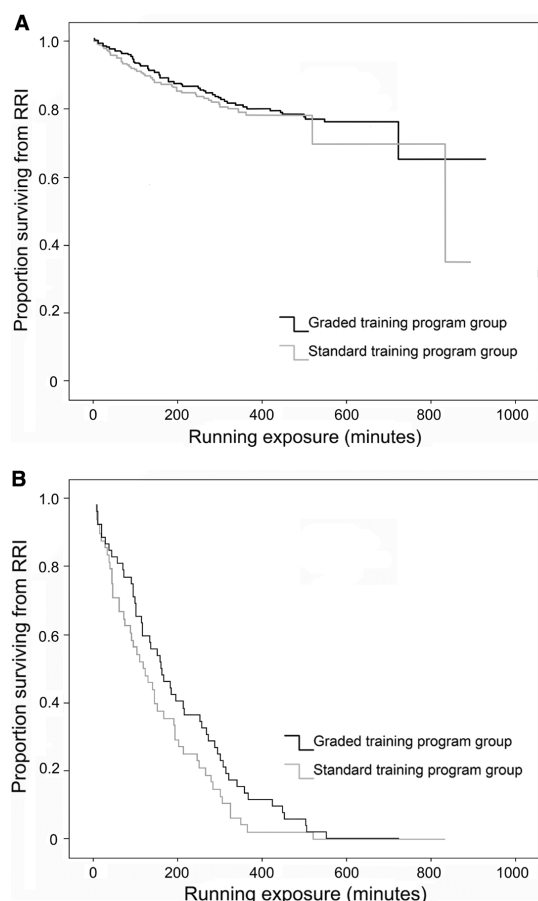


Figure 2. A, Kaplan-Meier plot of RRI (running-related injury) survival between all participants of the graded training program group and standard training program group. Approximately 80% in both groups stayed injury free. B, Kaplan-Meier plot of RRI survival between injured participants of the graded training program group and standard training program group.

TABLE 3
Incidence of RRI per 100 Runners at Risk and per 1000 Hours of Running Exposure in Graded and Standard Training Program Groups^a

	Graded Training Program (n = 250)	Standard Training Program (n = 236)	Total (N = 486)
Absolute number of RRIs	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)

^aRRI, running-related injury.

^bNumbers in parentheses represent 95% confidence interval.

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.⁶ 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. Hreljac⁹ 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.^{8,20}

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

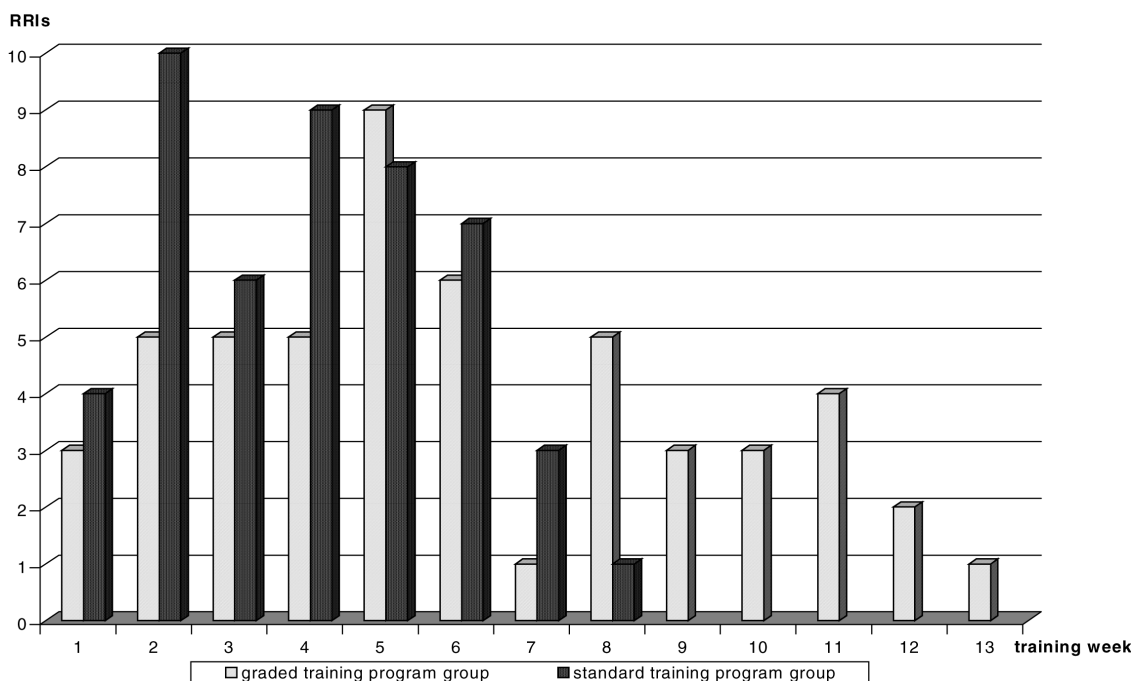


Figure 3. The absolute number of new running-related injuries (RRIs) per group in each week of the training program.

TABLE 4
Absolute Number and Percentage of RRIs
per Anatomical Site per Group^a

	Graded Training Program, n = 250 (% of injuries)	Standard Training Program, n = 236 (% of injuries)	Total N = 486 (% of injuries)
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.

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” study²⁴ 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 Run²⁴ 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,²⁴ 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.³ 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).³ 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.^{3,14,24} 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 study²⁴ 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.

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