



## Original research

# ProjectRun21: Do running experience and running pace influence the risk of running injury—A 14-week prospective cohort study



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## ABSTRACT

**Objectives:** The health benefits from participation in half-marathon is challenged by a yearly running-related injury (RRI) incidence proportion exceeding 30%. Research in injury etiology is needed to successfully prevent injuries. The body's load capacity is believed to play an essential role for injury development. Therefore, the purpose of ProjectRun21 was to investigate the association between load capacity defined as running experience and running pace, and RRI when following a specific half-marathon running schedule.

**Design:** A 14-week prospective cohort study.

**Methods:** A cohort of 784 healthy runners followed a specific half-marathon running schedule. Data on running activity was collected objectively using a Global-Positioning-System watch or smartphone. RRI were collected using e-mail-based weekly questionnaires. Primary exposures were running experience and running pace, dichotomized into a high and a low group for runners running less or more than 15 km/week and faster or slower than 6 min/km, respectively. Data was analysed through time-to-event models with cumulative risk difference (RD) as measure of association.

**Results:** A total of 136 participants sustained a RRI during follow-up. Although not statistically significant, all estimates indicate a tendency toward fewer injuries amongst runners categorized as having high experience (RD = -11.3% (-27.2% to 4.6%)) or high pace (RD = -17.4% (-39.0% to 4.5%)), and a combination of both high experience and high pace (RD = -8.1% (-22.3% to 6.1%)) compared with their counterpart peers.

**Conclusions:** Runners covering less than 15 km per week, and/or runs slower than 6 min/km, may sustain more RRI than their counterpart runners.

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## 1. Introduction

The interest in engaging into running a half-marathon has been steeply increasing the past 10 years.<sup>1,2</sup> This kind of physical activity has positive impacts on many health-related factors such as body weight and physical fitness.<sup>3,4</sup> Unfortunately, running-related injury (RRI) has been found to be the main reason for a temporary or even a permanent stop of running,<sup>5,6</sup> which together with a yearly time-loss defined running injury incidence proportion exceeding

30% for long-distance road runners<sup>7</sup> counterbalance all these health benefits.

Research in RRI etiology is therefore fundamental to provide runners with low injury risk training advises and for future development of low risk evidence-based tailored training schedules. Powered by various causal frameworks within sports injury science, training load is suggested to play a central and proximal role in the causal chain leading to injury.<sup>8–11</sup> Thus, training load is recommended to be analyzed as the primary exposure, while other variables like body composition, anthropometrics and equipment serves as effect-measure modifiers.<sup>8,12</sup> However, it has also been highlighted that RRI mainly develops as a consequence of overusing the body's tissue (muscles, tendons and bones),<sup>13</sup> leading to injury if the cumulative training load over one or more training sessions exceeds the runners' load capacity (constituted by e.g. diet habits,

**Abbreviations:** GPS, Global Positioning System; RRI, running-related injury; RD, risk difference.

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strength, illness status and history of previous injuries) for adaptive tissue repair.<sup>14,15</sup> This implies that the onset and development of RRI is strongly related to inappropriate management of training load in respect to the body's load capacity.<sup>8,9,15</sup> Since load capacity increases as a result of repeated adaptive running training, the level of running experience (expressed as weekly kilometres) as well as the running pace ability (expressed as minutes per kilometres) the runners possess prior to running participation could be used as proxies for load capacity, especially because direct measures of structure-specific capacities are challenging to measure in large scale epidemiological studies.

Previous studies on the influence of running experience and running pace on RRI development provided conflicting results.<sup>16</sup> One major explanation for this inconsistency may be due to unequal exposure to running between participants, which largely affects training load. As the risk of sustaining an RRI is believed to vary with changes in training load,<sup>17</sup> the latter has to be properly taking into account when investigating the association between running experience and/or running pace and injury development. Instead of controlling for training load differences in the analyses, training load can be taken into account by levelling the training load equally for all participants through the study design.<sup>8</sup> Then, runners with different load capacities are exposed to the same training load (follow the same running schedule) throughout follow-up, which allows for investigating the direct association between load capacity and injury development amongst runners following the same training program.<sup>8</sup> To our knowledge, this approach has not been previously used within the RRI research. Therefore, ProjectRun21 is the first study aiming to investigate the association between running experience and/or running pace and the risk of RRI amongst runners following the same 14-week running schedule (a distance-based, a pace-based or a mixed of those two) for half-marathon. We hypothesized that:

**H1.** Low experienced runners will sustain more injuries compared with high experienced runners during the first 50 km of following a distance-based 14-week running schedule for half-marathon.

**H2.** Low pace runners will sustain more injuries compared with high pace runners during the first 50 km of following a pace-based 14-week running schedule for half-marathon.

**H3.** Low pace runners with a low running experience will sustain more injuries compared with high pace runners with a high running experience during the first 50 km of following a mixed 14-week running schedule for half-marathon.

## 2. Methods

ProjectRun21 was designed as a prospective cohort study with 14-week follow-up. Runners were recruited during summer and fall 2016. Three different running schedules for half-marathon were developed for the project. The participants had to self-selected one of them during the registration process. Additionally, it was also possible to follow a self-structured running schedule if preferred. An overview of the inclusion flow and the follow-up process is provided in Fig. 1, while a detailed description of the study design and the running schedules has been published elsewhere.<sup>18</sup>

The study design, procedures, and informed consent were presented to the local ethics committee (record number "request 187/2015") who, according to Danish law, did not consider the study for any further ethical approval. The Danish data protection agency approved the study including the data collection procedures (The Danish Data Protection Agency's journal-number: 2015-57-0002; Aarhus University's journal-number: 62908, serial number 224). All participants provided written informed consent simulta-

neously with fulfilling the baseline questionnaire. Reporting of the study followed the STROBE statement.<sup>19</sup>

The study population was healthy runners at all levels of running ability. All interested runners were able to sign up for the study through an online-based baseline questionnaire. The questionnaire gathered information about demographical variables, previous and existing injuries, health status, use of the health-care system, previous and current running participation, use of running equipment (shoes and orthotics), and engagement into other sports activities. After fulfillment of the questionnaire, runners were screened for eligibility and were included if they were between 18 and 65 years, agreed to follow one of the available pre-developed running schedules or follow a self-structured schedule, agreed to use a Global Positioning System (GPS) watch or an application for Android- or iOS-based smart-phone to quantify their running, agreed to report running data (if any) via e-mails on a daily basis and agreed to fill out e-mail-based weekly questionnaires covering injury status, health status, use of the health-care system, changes in weight and participation in other sports.

Participants were excluded if they had sustained an RRI in the lower extremity or lower back 6 months preceding baseline, and/or had sustained any other injury limiting their running activity the past 6 months, and/or if any contraindications for vigorous physical activity were present: symptoms of heart or chest pain, previous heart or chest surgery, lung diseases, dizziness or discomfort when physically active, pregnancy or non-regulated diabetes.

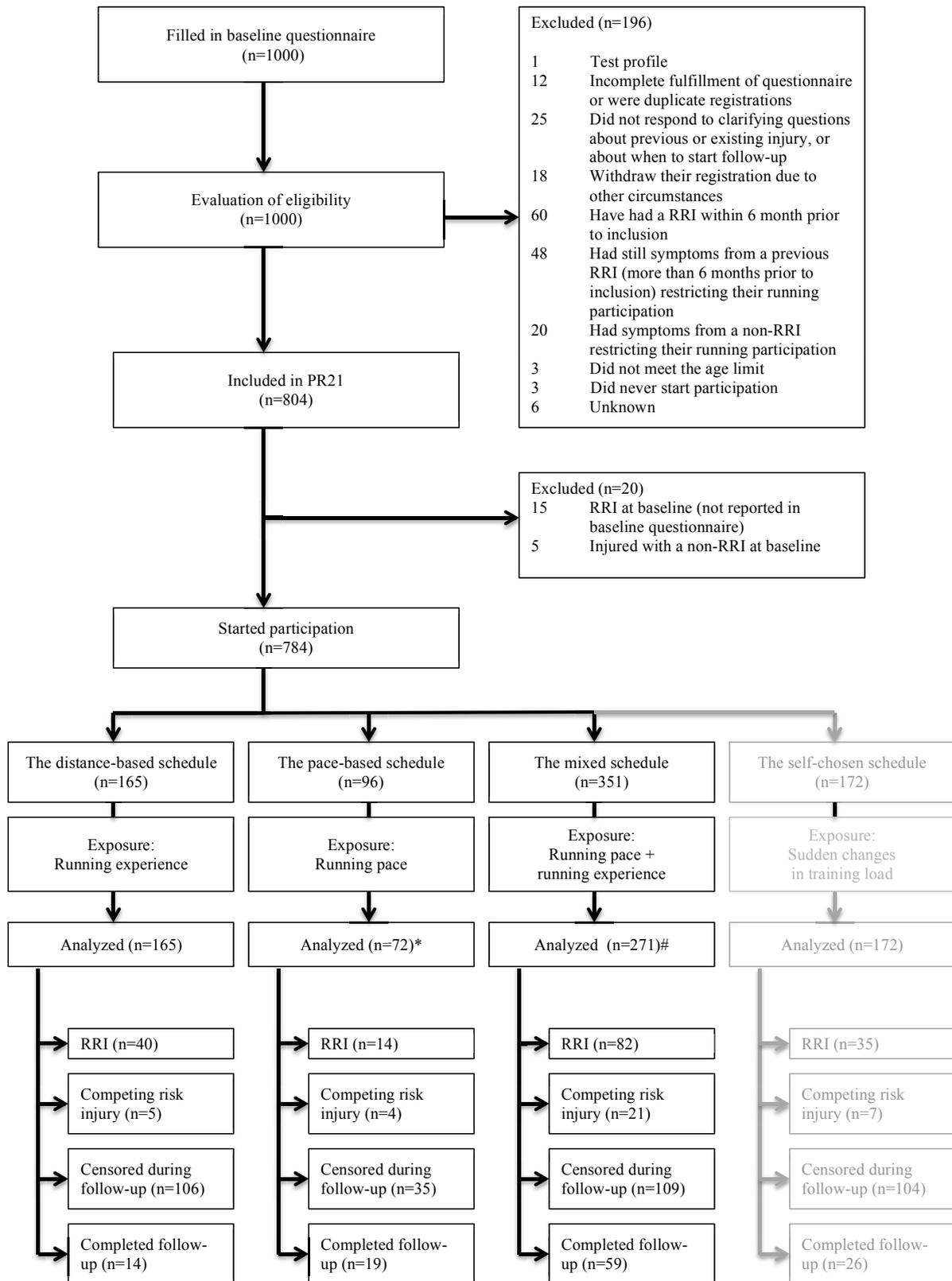
Data on running activity was collected objectively by the participants through a GPS-watch or an application for Android- or iOS-based smartphones. Subsequently, the data was uploaded manually to an Internet-based training diary (<http://www.mit-loebeprogram.dk>, Help2Run, Hornslet, Denmark) through automatically generated e-mails send out on daily basis by the system. As soon as the data was uploaded, it was accessible for the researchers and thus enabled for continuous surveillance of all runners.

The primary outcome of interest was RRI. The consensus-based injury definition (dichotomized as injury yes/no) recently developed by Yamato et al.<sup>20</sup> was used: "*Running-related (training or competition) musculoskeletal pain in the lower limbs that causes a restriction on or stoppage of running (distance, speed, duration, or training) for at least 7 days or 3 consecutive scheduled training sessions, or that requires the runner to consult a physician or other health professional*".

On a weekly basis, an additional e-mail was distributed to all participants allowing for uploading information regarding RRI and health the past week.

Running experience was the primary exposure for the cohort following the distance-based schedule, and running pace was the primary exposure for the cohort following the pace-based schedule. For the cohort following the mixed schedule, the primary exposure was a combination of both running experience and running pace. The data derived from the three different running schedules was utilized to investigate the association between the exposures and RRI independently of each other. To be precise, this means that the analyses of data only are performed for that specific running schedule from which they are gathered. The exposures were assessed once, and thus, were included in the analyses as time-fixed variables. As the training load was not kept identical to all participants following the self-structured running schedule, data from this schedule was not included in the analyses for the present paper.

Information regarding running experience was collected through the baseline questionnaire asking questions about how many kilometers the runners usually had been running per week over the past 6 months prior to inclusion. The timespan on 6 month was chosen superior to e.g. 12 month in order to provide an up-to-



**Fig. 1.** Flow chart of the inclusion and follow-up process.

PR21 = ProjectRun21. \* 24 participants following the pace-based schedule were excluded in the analysis due to inadequate registration of the start-test data. # 80 participants following the mixed schedule were excluded in the analysis due to inadequate registration of the start-test data. The information related to the self-chosen schedule is marked in grey, as these data are not included in the analyses in this article.

**Table 1**  
Baseline characteristics for all participants, and for each exposure group in accordance to each running schedule. Numbers are presented as means  $\pm$  SD, percentage, and as median with interquartile range for age and the running variables. RRI = running-related injury. kg = kilograms. cm = centimeter. km = kilometer. min = minutes. min/km = minutes per kilometer. \* 24 participants following the pace-based schedule were excluded in the analysis due to inadequate registration of the start-test data. # 80 participants following the mixed schedule were excluded in the analysis due to inadequate registration of the start-test data.  $\diamond$  more than 6 month prior to inclusion.  $\ddagger$  at baseline. The information related to the self-chosen schedule is marked in grey, as these data are not included in the analyses in this article.

Baseline characteristics	Distance-based schedule		Pace-based schedule		Mixed schedule				Self-chosen schedule	All
	n=165		n=96 (72)*		n=351 (271)#				n=172	n=784
	Running experience		Running pace		Running experience and running pace					
Exposure	Low (n=130)	High (n=35)	Low (n=18)	High (n=54)	Low/low (n=53)	High/low (n=12)	Low/high (n=143)	High/high (n=63)		
<b>Demographics</b>										
- Age (years)	36 (26-45)	41 (31-50)	31 (26-45)	39 (30-45)	37 (28-44)	42 (34-49)	36 (28-44)	40 (33-47)	40 (31-48)	37 (29-46)
- Gender										
Female	85 (65.4%)	18 (51.4%)	16 (88.9%)	25 (46.3%)	40 (75.5%)	8 (66.7%)	86 (60.1%)	38 (60.3%)	118 (68.6%)	507 (64.7%)
Male	45 (34.6%)	17 (48.6%)	2 (11.1%)	29 (53.7%)	13 (24.5%)	4 (33.3%)	57 (39.9%)	25 (39.7%)	54 (31.4%)	277 (35.3%)
- Body mass (kg)	76.3 $\pm$ 17.0	76.6 $\pm$ 11.8	75.7 $\pm$ 13.4	73.1 $\pm$ 12.2	72.6 $\pm$ 13.0	76.0 $\pm$ 18.2	72.7 $\pm$ 10.6	73.1 $\pm$ 12.1	72.3 $\pm$ 13.1	73.6 $\pm$ 13.6
- Height (cm)	172.9 $\pm$ 9.8	174.7 $\pm$ 8.1	170.6 $\pm$ 5.3	175.9 $\pm$ 8.0	171.8 $\pm$ 8.3	170.1 $\pm$ 9.4	174.3 $\pm$ 7.9	174.5 $\pm$ 7.6	172.9 $\pm$ 9.6	173.4 $\pm$ 9.0
<b>Running</b>										
- Experience (months)	36 (12,60)	72 (24-120)	36 (6-72)	66 (48-144)	60 (36-120)	48 (36-78)	60 (36-120)	60 (48-180)	60 (36-126)	60 (24-120)
- Average weekly distance (km)	5 (2-8)	16 (15-20)	6.5 (0-10)	10 (5-16)	5 (3,5-6)	19 (15-20)	6.5 (5-10)	17 (15-20)	16 (10-25)	10 (5-15)
- Completed HM previously										
Yes	50 (38.5%)	15 (42.9%)	3 (16.7%)	35 (64.8%)	25 (47.2%)	7 (58.3%)	74 (51.8%)	45 (71.4%)	117 (68.0%)	426 (54.3%)
No	80 (61.5%)	20 (57.1%)	15 (83.3%)	19 (35.2%)	28 (52.8%)	5 (41.7%)	69 (48.2%)	18 (28.6%)	55 (32.0%)	358 (45.7%)
<b>Injury</b>										
- Previous RRI $\diamond$										
Yes	38 (29.2%)	11 (31.4%)	3 (16.7%)	22 (40.7%)	18 (34.0%)	5 (42.0%)	47 (32.9%)	27 (42.9%)	65 (37.8%)	268 (34.2%)
No	92 (70.8%)	24 (68.6%)	15 (83.3%)	32 (59.3%)	21 (66.0%)	7 (58.0%)	96 (67.1%)	36 (57.1%)	107 (62.2%)	516 (65.8%)
- Previous other sports injuries $\diamond$										
Yes	22 (16.9%)	10 (28.6%)	3 (16.7%)	14 (25.9%)	7 (13.2%)	1 (8.3%)	24 (16.8%)	12 (19.1%)	24 (14.0%)	130 (16.6%)
No	108 (83.1%)	25 (71.4%)	15 (83.3%)	40 (74.1%)	46 (86.8%)	11 (91.7%)	119 (83.2%)	51 (80.9%)	148 (86.0%)	654 (83.4%)
<b>Other sports</b>										
- Participation in other sports $\ddagger$										
Yes	66 (50.7%)	18 (51.4%)	10 (55.6%)	39 (72.2%)	27 (50.9%)	7 (58.3%)	92 (64.3%)	40 (63.5%)	99 (57.6%)	462 (58.9%)
No	64 (49.3%)	17 (48.6%)	8 (44.4%)	15 (27.8%)	26 (49.1%)	5 (41.7%)	51 (35.7%)	23 (36.5%)	73 (42.4%)	322 (41.1%)

date picture of the runners currently running experience. Running experience was dichotomized into a high experience group running 15 km or more per week and a low experience group running less than 15 km per week.

Running pace was measured as minutes/kilometer and obtained via a 2 km max start-test embedded in the pace-based running schedule on week one, training session two. Running pace was also dichotomized into a high pace group running faster than 6 min/km and a low pace group running slower than 6 min/km.

The chosen pre-fixed cut-off values for both exposures were set a priori data collection based on two previous studies collecting data on average running distance per week and average running pace from a total of 925 novice and recreational runners.<sup>21,22</sup>

The statistics for investigating the association between running experience and/or running pace and the risk of RRI was performed using time-to-event statistics (pseudo-observation method through a generalized linear regression model). Runners were censored in case of discontinuation of the running schedule for any reason. Cumulative risk difference (RD) was used as measure of association<sup>23</sup> for time-to-first-injury comparing groups within each exposure. For the primary analysis, we used kilometers as time-scale and 50 km as time-point. For the secondary analyses, we analyzed data after 100 km, 200 km and by the end of follow-up. Secondary analyses were also performed with weeks and training sessions as time-scales. With weeks as time-scale, data was analyzed at 2, 4, 8 and 14 weeks, and with training sessions as time-scale; data was analyzed after 6, 12, 24 and 42 sessions.

Competing risk analysis, using the Aalen-Johansen estimator, was performed separately for both exposures in order to take into account that runners can also sustain injuries from other sports competing to RRI during follow-up.<sup>24</sup>

In order to avoid violation of the statistical assumptions for valid statistical analyses, Hansen et al.<sup>25</sup> found that at least 10 events (injuries) are needed per variable when using the pseudo-observation method to estimate risk differences examining sample sizes of 50 and above. It was our intention to include BMI, age, previous injury, and participation in other sports activities as effect-measure modifiers in the analyses, and to investigate the interaction between running experience and running pace on injury development. However, since robust statistical analyses of such analyses are dependent on a considerable number of injury events in each exposure group, performance of these analyses was not possible due to an insufficient number of injuries.<sup>25</sup>

Study power was calculated independently for the two time-fixed exposures using a superiority model. Based on previously collected data, a cumulative injury incidence of 12% was expected for high experienced/high-pace runners,<sup>26</sup> while 40% for their counterpart peers.<sup>27</sup> To be able to show a minimum difference of 5% in injury risk between groups of running experience and 3% between groups of running pace, and to take 20% potential loss to follow-up into account<sup>28</sup>, a sample size of respectively 138 and 108 runners for the two exposure groups was needed in order to reach a desired power of 80%.

The primary analysis was performed based on the assumption that the runners were compliant to their selected running schedule. Results are presented with estimated precision (95% confidence interval), and is considered statistically significant at  $p < 0.05$ . In addition, for proper interpretation of study results, estimated effect size and estimated precision (95% confidence limits) were calculated. All statistical analyses were conducted using STATA version 12 or later.

**Table 2**

Primary analyses. All estimates are presented after 50 km of completed follow-up. RD = risk difference. CI = confidence interval. The cumulative injury incidence proportion for the runners with low pace (slower than 6 min/km) were = 25.2% (4.8%–45.7%), for the runners with low experience (less than 15 km/week) = 21.5% (12.2%–30.8%) and for the runners with a combination of low experience and low pace = 19.5% (8.2%–30.8%). Values with bold are total numbers in each schedule.

Exposure groups	Number of participants	RD	95% CI	p Value
Pace based schedule	<b>72</b>			
Low pace (ref.)	18	0		
High pace	54	–17.4%	–39.0% to 4.5%	0.119
Distance based schedule	<b>165</b>			
Low experience (ref.)	130	0		
High experience	35	–11.3%	–27.2% to 4.6%	0.162
Mixed schedule	<b>271</b>			
Low experience/low pace (ref.)	53	0		
High experience/low pace	12	–19.4%	–31.0% to –7.9%	0.001
Low experience/high pace	143	–7.2%	–19.9% to 5.5%	0.264
High experience/high pace	63	–8.1%	–22.3% to 6.1%	0.263

### 3. Results

A total of 784 runners were included in the study. An overview of the inclusion flow and the follow-up process is provided in Fig. 1. A description of the baseline characteristics for all participants, and for each exposure group in accordance to each running schedule is presented in Table 1. A total of 612 runners chose to follow one of the three pre-designed running schedules (165, 96 and 351 followed the distance-based, pace-based and mixed-based running schedule, respectively) while 172 runners chose the self-structured schedule. Out of the 612 runners following one of the three pre-designed schedules, 104 were excluded from the analyses due to inadequate registration of the start-test data. Eventually, 508 runners were included in the analyses for the present paper. Collectively, they participated in 3.422 weeks (774, 583 and 2.065 weeks for the distance-based, the pace-based and the mixed schedules, respectively), covered 51.710 km (11.700, 7.910 and 32.100 km for the distance-based, the pace-based and the mixed schedules, respectively), and completed 7.928 running sessions (1.596, 1.430 and 4.902 sessions for the distance-based, the pace-based and the mixed schedules, respectively) until first injury or censoring.

Across all running schedules, a total of 136 participants (20%) sustained an RRI during follow-up. Of the 136 injuries, 40 occurred amongst runners following the distance-based running schedule, 14 amongst those following the pace-based running schedule and 82 amongst those following the mixed schedule. The cause-specific Aalen-Johansen injury plots, and the results for the different running schedules using different time scales and different time points are shown in Supplementary material S1 and S2, while the results for the primary analyses are specified in Table 2. Although not statistically significant, all estimates indicate a tendency toward fewer injuries occurred amongst runners categorized as having high experience (RD = –11.3% (–27.2% to 4.6%)) or high pace (RD = –17.4% (–39.0% to 4.5%)), and for runners with both high experience and high pace (RD = –8.1% (–22.3% to 6.1%)) compared with runners having low experience and/or low pace (see Table 2).

### 4. Discussion

The main purpose of ProjectRun21 was to investigate the association between running experience and/or running pace and the risk of running-related injury amongst runners following the same 14-week running schedule for half-marathon during the first 50 km of running. We hypothesized that runners with low running experience (running less than 15 km per week), and/or a low running pace (running slower than 6 min/km) at baseline would be more prone of sustaining an RRI during the compared with their counterpart runners. Although not statistically significant, the results from the present study point in the direction of our hypothesis by showing

a trend toward fewer runners categorized as having high experience, high pace, or a combination of both high experience and high pace sustain injuries compared with their counterpart runners (see Table 2). Despite statistical significance of the estimate for the high experience/low pace exposure group in the mixed schedule, caution must be taken when interpreting this result, as the number of injuries recorded in this group was too low to meet the assumptions for performing robust statistical analyses.<sup>25</sup>

These findings from the primary analyses are fostered by the analyses in the secondary analyses using different time-scales and different time-points shown in the cause-specific Aalen-Johansen injury plots in Supplementary material S1 and S2.

Despite the large risk differences found between the exposure groups, the estimates did not reach statistical significance. This may be explained by a lower cumulative injury incidence proportion than expected, which in turn might be partially due to 1) an unexpected high number of participants who were censored prior to the end of the follow-up due to discontinuation of the running schedule for other reasons than RRI and 2) the total of 104 participants who were excluded from the analyses of the pace-based and the mixed schedule due to inadequate registration of the start-test data needed for categorization of the running pace exposure.

In the existing literature investigating the association between running experience and/or running pace and development of RRI risk, inconsistent results have been reported.<sup>16</sup> The definition of the main exposures, how they are measured and quantified, and large differences in training regimen between participants may explain this lack of consistency. The results from the present study add new information to these conflicting results as the study design aimed to expose all participants to a fixed training regime with a fixed training load. This approach cancels out the impact of different levels of training load, and thereby opens up for a more direct measure of the influence of running experience and running pace on the development of RRI.

As training load has been suggested to play an essential role for RRI development, one strength of the current study was the use of weekly kilometres as a measure of running experience instead of using measures of cumulative yearly or monthly units of running as utilized in previous studies. Indeed, two runners with the same monthly or yearly running experience could have been running a different amount of weekly kilometres allowing for a large variation in cumulated training load. Other strengths of the current study were: the prospective design with close surveillance of more than 780 runners included, the objective measurement of running data using GPS, the advanced statistical methods used, and the possibility for the runners to self-select the running schedule they preferred.

A possible source of risk of bias was the data collection of RRI. Compared to the advantage of using clinical hands-on examina-

tions of injuries, potential information bias could have occurred in relation to the self-reporting of injury status. In addition, due to the design of the present study, some levels of confounding and effect-measure modification cannot be precluded. Further, possible non-compliance may have confounded the main analyses in the present study,<sup>29</sup> since the study was based on the assumption that the runners were compliant to their selected running schedule. In relation to effect-measure modification, other co-variants such as body composition, age, previous injury, and participation in other sports activities may also have influenced the results, as these variables are believed to have a modifying effect on the training load.<sup>12</sup> For example, age might be associated with running experience expressed in cumulated months of practice (Table 1). However, due to the low number of RRI reported, it was not possible to perform stratified analyses on these variables as effect-measure modifiers, or to run analyses on a possible interaction between running experience and running pace.<sup>25</sup> As multiple risk factors influence each other in the causal puzzle toward RRI, the findings from the present study allow for conclusions based on associational interference,<sup>30</sup> but are unable to explain the causal mechanisms behind RRI. Importantly, this means that it still remains uncertain if interventions related to running experience and running pace can be used to prevent RRI. Yet, it suggests that clinically awareness from runners, coaches, sports organizations, running clubs and healthcare professionals should be put into that more injuries are likely to occur in runners whose running experience is lesser than 15 km/week and/or running slower than 6 min/km when taking up a running schedule for half-marathon.

## 5. Conclusion

The findings from the present study visualizes to runners, coaches, sports organizations, running clubs and health-care professionals that the specific sub-group of runners that covers less than 15 km per week, and/or runs slower than 6 min/km may be more vulnerable of sustaining a running-related injury compared with their counterpart runners. However, the incidence of RRI in the present study was too low to allow for taken into account the influence of other RRI risk factors and how they are influencing each other in the causal puzzle toward RRI. Therefore, the findings from the present study inform the associational interference between running experience and/or running pace and the development of RRI. Importantly, why runners sustain injury, and whether interventions related to running experience and running pace can be used to prevent RRI, still remain speculative.

## Practical implications

- Runners covering less than 15 km per week, and/or runs slower than 6 min/km seems to be more vulnerable of sustaining a running-related injury compared with their counterpart runners following the same 14-week running schedule for half-marathon.
- It still remains uncertain if preventive interventions related to running experience and running pace have a protective effect on the risk of sustaining a running-related injury when following a running schedule for half-marathon.
- Running experience defined as running distance could refer to the actual running exposure over a past period, since this seems a more direct measure of training load.

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This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

## Ethics approval

The study design and its procedures was presented the 15th September 2015 to the local ethics committee (record number “request 187/2015”) who, according to the Danish law, did not consider the study for ethical approval, owing to the observational nature of the study.

The Danish data protection agency approved the study including the data collection procedures (The Danish Data Protection Agency's journal-number: 2015-57-0002; Aarhus University's journal-number: 62908, serial number 224). Registered the 2nd March 2016.

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## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.jsams.2018.08.014>.

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