THE START-TO-RUN DISTANCE AND RUNNING-RELATED INJURY AMONG OBESE NOVICE RUNNERS: A RANDOMIZED TRIAL

Michael Lejbach Bertelsen¹

Mette Hansen¹

Sten Rasmussen^{2,3}

Rasmus Oestergaard Nielsen¹

ABSTRACT

Background/Purpose: High body mass index is associated with an increased risk of running-related injury among novice runners. However, the amount of running participation plays a fundamental explanatory role in regards to running-related injury development. Therefore, the purpose of the present study was to investigate if the risk of running-related injury among obese novice runners (BMI 30-35) was different when the start-to-run distance was 3km per week instead of 6km per week.

Hypothesis: A start-to-run distance of 3km per week is associated with 20% fewer running-related injuries and significantly fewer symptoms of overuse injury than a start-to-run distance of 6km per week among obese novice runners.

Study design: Randomized trial

Methods: Fifty-six obese novice runners with a body mass index between 30-35 were enrolled and randomized to receive one of the two following Interventions: (i) a 4-week running program with a start-to-run distance of 3km per week including three sessions with 1km running per session (n=29), or (ii) a 4-week running program with a start-to-run distance of 6km per week including three sessions with 2km running per session (reference group, n=27). In both programs, the weekly running distance was increased by 10% each week throughout the follow-up.

Results: The intention-to-treat analysis revealed a protective cumulative risk difference of -16.3% (95%CI: -43.8%; 11.3%, p=0.25) after four weeks. Importantly, some participants completed much more running than prescribed (n=5) and some never uploaded any training (n=15). Therefore, a supplementary per-protocol analysis was performed revealing a cumulative risk difference of -31.2% (95%CI: -57.0%; -5.2%, p=0.02) after four weeks. Furthermore, in the per-protocol analysis, the cumulative risk difference of overuse-injury symptoms was -47.8% (95%CI: -81.0%; -14.6%, p=0.01) after four weeks of running

Conclusions: A 3km reduction from 6km per week to 3km per week in the start-to-run distance appears to be associated with fewer running-related injuries and significantly fewer symptoms of overuse injury.

Key words: Movement System, Novice runner, Obese, Running, Running-related injury, Training dose

Level of evidence: 2b

CORRESPONDING AUTHOR

Michael Lejbach Bertelsen

Department of Public Health, Section for
Sport Science, Aarhus University,
Dalgas Avenue 4, 8000 Aarhus C, Denmark.

E-mail: michael.bertelsen@ph.au.dk

Phone +45 87 16 84 92

¹ Section for Sport Science, Department of Public Health, Aarhus University, Denmark

² Orthopedic Surgery Research Unit, Aalborg University Hospital, Denmark

³ Department of Clinical Medicine, Aalborg University, Denmark

Conflict of interest

The authors declare no conflict of interest.

INTRODUCTION

Running is highly effective at promoting numerous health-related benefits related to body mass, body fat, resting heart rate, VO₂max, triglycerides, and HDL cholesterol in physically inactive adults.¹ Furthermore, running is associated with a 30% lower risk of all-cause mortality and a 50% lower risk of cardiovascular mortality.² Notwithstanding the many health benefits, running-related injuries are a well-known problem to runners and clinicians. The yearly cumulative injury risk of running-related injury is 19.4% to 79.3% depending on the population and the injury definition used.³⁻⁵ In this regard, obese novice runners seem particularly at risk of injury. Three large-scale prospective cohort studies among novice runners all found an association between higher body mass index (BMI) and increased risk of running-related injury.⁶⁻⁸ Running-related injury can lead to long periods of absence from running or even a permanent stop.⁹⁻¹² Hence, injury prevention specifically targeted obese novice runners is important to ensure their successful inclusion and long-term commitment to running.

The amount of participation plays a fundamental explanatory role in regards to the risk of sustaining a running-related injury.¹³⁻¹⁵ This has been visualized by a framework for the etiology of running-related injuries.¹³ This framework builds on the premise that running-related injury occurs because of a mismatch between the cumulative load of one or more running sessions and the structures capacity to handle that load (the former surpasses the latter). Based on the outlined framework, the explanatory mechanism could be: (i) Obese novice runners are at an enhanced risk owing to a higher load magnitude per stride. Because of the higher body weight, fewer strides are potentially needed to accumulate an injurious amount of load when obese individuals take up running. (ii) Obese individuals may have a lower structure-specific load capacity than normal-weight novice runners when running is initiated owing to the sedentary lifestyle, which is associated with obesity.¹⁶ Consequently, the obese novice runner is less prepared to handle the load during running compared with the normal-weight novice runner who may have adapted in advance by being physical active in other weight-bearing

sport activities. Fortunately, both mechanisms can be defused by reducing the number of strides/distance accordingly and thereby control the cumulative load at a non-injurious level. This would allow positive adaptations to take place to enhance the structure-specific load capacity before the distance is increased.¹³

Nielsen et al have recently investigated whether the risk of running-related injury differed in obese (BMI >30 kg/m²) and non-obese (BMI <30 kg/m²) novice runners that initiated running with different weekly start-to-run distances.¹⁷ They found obese novice runners to have a 10.8% greater cumulative risk of running-related injury after 20km when the start-to-run distance was >6km the first week compared with <3km.¹⁷ In comparison, non-obese novice runners had -1.0% lower cumulative risk of running-related injury after 20km when the start-to-run distance was >6km the first week compared with <3km.¹⁷

Nielsen et al concluded that novice runners with BMI >30 kg/m² should be recommended a cumulative dose of running of <3km the first week. However, owing to the limitations of their study design, randomized trials are needed to further explore the effect of these recommendations.¹⁷ More knowledge on the appropriate start-to-run distance for obese novice runners can potentially allow a greater number of persons with obesity to take up running and harvest the many health-benefits running has to offer, without sustaining running-related injury.

Therefore, the purpose of the present study was to investigate if the cumulative incidence proportion of running-related injury among obese novice runners with BMI 30-35 was different when the start-to-run distance was 3km per week instead of 6km per week. It was hypothesized that a start-to-run distance of 3km per week would be associated with 20% fewer running-related injuries and significantly fewer symptoms of overuse injury.

METHODS

Study design

The study was a randomized trial (unblinded) with a 4-week follow-up. Reporting of the study followed the CONSORT statement.¹⁸ The study was conducted in Denmark and the Ethics Committee of Northern

Denmark Region (N-20160031) approved the design, procedures, and informed consent procedures. The study was accepted by the Danish Data Protection Agency. All participants provided written informed consent.

Participants

The recruitment took place from May 2016 to September 2016 and was assisted by video material and written information posted on social media (Facebook). Furthermore, recruitment material was distributed to the employees and students of large public institutions in central Jutland (Via University College, Aarhus University and Central Denmark Region) through their professional e-mail or intranet account. Individuals who were interested in participating completed an online questionnaire, which contained questions about gender, age, running experience, health, previous running-related injuries and non-running-related injuries. Individuals with BMI 30-35, age 18-65 years, no previous running experience (less than 10km combined the last year) and less than one hour of other sports activity per week within the past year were eligible to participate. Individuals were excluded prior to baseline if they had absolute contraindications for vigorous physical activities,¹⁹ a new injury or symptoms from an older injury in the lower extremities within the last two years, or were unwilling to monitor their running training using a GPS-watch or a smartphone application. Persons eligible for inclusion were contacted by phone to verify their eligibility, give verbal information about the purpose and the content of the study, and to make a baseline appointment. Ineligible persons received an e-mail explaining why they were excluded.

Baseline assessment and randomization procedure

The baseline assessment took place at Aarhus University, Department of Public Health, Section for Sports Science, Dalgas Avenue 4, 8000 Aarhus C, Denmark from June 2016 to September 2016. At baseline, eligibility was confirmed once again using a checklist on in- and exclusion criteria. The height of the participants was measured by a ruler and the weight by a calibrated personal scale (SC 330; Tanita Corporation, Tokyo, Japan). BMI was

calculated based on these baseline-measurements (kg/m^2). Finally, the blood pressure was measured and assessed according to the guidelines from the Danish Hypertension Society to ensure the safety of the participants before final inclusion in the study. After the baseline measurements were completed, the participants were randomly assigned to one of two possible interventions following simple randomization procedures by selecting a sealed envelope containing one of two possible running programs. The participants were not told which intervention they were assigned. However, they were aware that the purpose of the study was to compare injury risk difference between a “standard” and a “reduced distance” program. Thus, they were probably able to identify the intervention by viewing the cumulative start-to-run distance the first week and compare it to other “standard” running programs. All enrollment and assignment procedures were carried out by the same principal investigator (MLB).

Interventions

Three kilometer (3km): Running program with a cumulative running distance of 3km the first week (1km per session). The program consisted of four weeks with three weekly training sessions. The running distance was increased by $\sim 10\%$ per week. The specific details of the running program are shown in Table 1.

Six kilometer (6km): Running program with a cumulative running distance of 6km the first week (2km per session). The program consisted of four weeks with three weekly training sessions. The running distance was increased by $\sim 10\%$ per week. The specific details of the running programs are shown in Table 1.

All participants were instructed to have at least one day with no running between each session and to run with a moderate intensity i.e. being able to converse without breathlessness. The running distance in both programs was split up into shorter intervals with walking at an easy/comfortable pace in the pauses between each interval. The running was conducted on a self-chosen route. Each week participants received a link to an online questionnaire via e-mail. In the weekly questionnaire, they reported their running training on a session level

Table 1. The 3km and 6km intervention running programs.

	Session 1		Session 2		Session 3	
	3km	6km	3km	6km	3km	6km
Week 1	500m walk	500m walk	500m walk	500m walk	500m walk	500m walk
	500m run	500m run	500m run	500m run	500m run	500m run
	200m walk	200m walk	200m walk	200m walk	200m walk	200m walk
	500m run	500m run	500m run	500m run	500m run	500m run
		200m walk		200m walk		200m walk
Week 2		500m run		500m run		500m run
	500m walk	500m walk	500m walk	500m walk	500m walk	500m walk
	500m run	500m run	500m run	500m run	500m run	500m run
	200m walk	200m walk	200m walk	200m walk	200m walk	200m walk
	600m run	500m run	600m run	500m run	600m run	500m run
Week 3		200m walk		200m walk		200m walk
		600m run		600m run		600m run
	500m walk	500m walk	500m walk	500m walk	500m walk	500m walk
	500m run	500m run	600m run	500m run	600m run	600m run
	200m walk	200m walk	200m walk	200m walk	200m walk	200m walk
Week 4	600m run	600m run	600m run	600m run	750m run	600m run
		200m walk		200m walk		200m walk
		600m run		600m run		600m run
		200m walk		200m walk		200m walk
		700m run		700m run		700m run
Week 4	500m walk	500m walk	500m walk	500m walk	500m walk	500m walk
	500m run	600m run	500m run	600m run	500m run	600m run
	200m walk	200m walk	200m walk	200m walk	200m walk	200m walk
	700m run	600m run	800m run	600m run	1000m run	600m run
		200m walk		200m walk		200m walk
		600m run		700m run		700m run
		200m walk		200m walk		200m walk
		700m run		700m run		1000m run
The 3km intervention program had a total running distance of 3km the first week. The 6km intervention program had a total running distance of 6km the first week. All runners were instructed to have at least one day between each session and run with a moderate intensity i.e. being able to converse without breathlessness. The running distance was increased by approximately 10% per week in both programs.						

the past week, their injury status, and overuse symptoms status. The distance of each training session was reported in meters. The participants were instructed to measure their running distance with a smartphone application or a running-watch, of their choice, using Global Positioning System (GPS). GPS measurement of the distance is recommended in scientific studies because runners are unable to subjectively evaluate their running distance in a

valid manner.²⁰ The measurement error of commercial GPS running watches ($\leq 6.2\%$) is acceptable in terms of identifying relevant differences in running distances in scientific studies on running-related injuries.²¹ The participants automatically received a reminder e-mail if they failed to complete the weekly questionnaire within five days after receiving it. They were contacted by phone if they did not respond to the reminder e-mail within one week.

Outcome measures

Running-related injury (primary outcome)

Running-related injury was operationally defined for this study as: *An injury sustained on muscles, joints, tendons and / or bones as a result of running. The injury must have caused the runner to reduce the intended training (reduced distance, intensity or frequency).* This injury definition was a modified version of the one-day training-reduction injury (TR-day) and one-day time-loss injury (TL-day) definition used by Kluitenberg et al.²² Each week, in connection with their training registration, participants were asked if they had to reduce the training (reduced distance, intensity) owing to a running-related injury. This was reported for each of the weekly training sessions. If participants skipped entire training sessions, they had to report if it was because of a running-related injury (reduced frequency) or another reason.

Symptoms of overuse injury (secondary outcome)

Symptoms of overuse injury were operationally defined for this study as: *A physical problem perceived as pain, tenderness, stiffness, aching, looseness, locking or instability in any part of the body, caused by running.* This definition was adapted from the Oslo Sports Trauma Research Center questionnaire on overuse injury (OSTRC-O).²³ At the end of each week, in connection with their training registration, participants were asked to report any symptoms of overuse injury they had during the past week. Participants that reported to have had *"a physical problem perceived as pain, tenderness, stiffness, aching, looseness, locking or instability in any part of the body, caused by running"* in the past week were asked to complete the OSTRC-O questionnaire.²³ The OSTRC-O questionnaire was a validated Danish translation of the original questionnaire.²⁴ The symptoms were reported on anatomical location level (ankle, knee, hip etc.). The severity of the symptoms was described using the OSTRC-O questionnaire severity score.^{23,24} The severity score was regarded as a rank score and further categorized according to the approach used by the Oslo sports trauma research center in other studies^{23,25,26}: No problem (severity score of 0), problem (severity score above 0) and substantial problem (OSTRC severity score of 13 or above in question 2 and/or question 3) were operationally defined.

Power calculation

An observational prospective cohort study found a running-related injury risk of 11.9% and 22.7% among obese runners running less than 3km the first week, and more than 6km the first week, respectively.¹⁷ Therefore, an expected running-related injury risk difference of minimum 10% between the 3km and 6km interventions seemed reasonable. A superiority power equation, with a minimal important difference of 10%, an alpha set to (0.05) and 62 participants in each exposure group, estimated the study power to 80%. We aimed to recruit and enroll $n = 140$ participants to take a dropout into account.

Statistical analyses

Descriptive data for the demographic characteristics were presented as counts and percentage for dichotomous data. Continuous data were presented as mean, standard deviation (SD) or median and (25th percentile, 75th percentile) for normal and non-normal distributed data, respectively. The risk of running-related injury and risk of symptoms of overuse injury were assessed using a time-to-event analysis with weeks as the time scale. The pseudo-observation method²⁷ was applied to determine the cumulative risk difference (CRD) between the two interventions at week two and four (time-points were predefined in the study protocol). CRD is an absolute measure of association and a negative CRD indicates a protective effect (percentage point decrease in risk). In addition, a supplementary analysis with distance in km as the time scale and CRD estimated at 10km and 20km was performed in order to compare the results with the study from Nielsen et al.¹⁷ All participants randomized were included in the analysis. Participants were censored when the outcome of interest occurred or they had no additional training uploads for the remainder of the follow-up. Importantly, censoring is not similar to exclusion. All censored participants are included in the analysis but they were only at risk until the censoring occurred.²⁷ Only the first injury and symptom was included in the main and secondary outcome analysis, respectively. All estimates were presented with a 95% confidence interval and a p-value. Differences were considered statistically significant at $p < 0.05$.

A supplementary per-protocol analysis was performed. In the per-protocol analysis, participants

were excluded if they did not upload any running during the follow-up. Participants were censored if their training exceeded 130% of the scheduled distance in a training session, the outcome of interest occurred, or they had no additional training uploads for the remainder of the follow-up.

RESULTS

Participant flow

A total of 140 persons signed up for the study by answering the online inclusion questionnaire. Of these, 56 eligible persons were contacted for baseline assessment and randomization after excluding 84 persons. The specific reasons for exclusion are presented in the flow diagram (Figure 1). The recruitment ended before reaching the intended sample size of 140 subjects because it was exceedingly difficult to find additional eligible participants, within a reasonable timeframe, without the need for additional funding.

The randomization procedure assigned 29 participants to the 3km intervention and 27 participants to the 6km intervention. All participants who underwent randomization were included in the main time-to-event analysis (intention-to-treat). Figure 1 presents the flow of the participants from enrollment to the time point they were injured or censored.

Baseline data

The demographic characteristics of the participants are presented in Table 2 according to intervention allocation.

Compliance

Non-injured participants in the 3km intervention group completed half of the scheduled sessions 169 of 324 (52%). The proportion of completed sessions in the 6km intervention group was 120 of 264 (45%). The total distance (both running and walking) completed by the non-injured participants compared with the total distance scheduled was 309 of 603km (51%) in the 3km intervention and 404 of 902km (45%) in the 6km intervention. The reasons for discontinuing the interventions before end follow-up are presented in Figure 1. A total of four participants in the 3km intervention and one participant in the 6km intervention did not report why they discontinued

the intervention and did not answer their phone or e-mail. None of the participants who discontinued the 3km intervention for unknown reason reported any symptoms the week prior to leaving the intervention. The participant in the 6km intervention reported symptoms the week before discontinuing the intervention (OSTRC Severity score = 31).

A small group of participants deviated severely from their scheduled training and trained much more than prescribed. Collectively, five participants completed 16 sessions that each exceeded 130% of the scheduled distance. All participants who trained excessively had been allocated to the 3km intervention. Two of the five participants sustained an injury subsequently to exceeding the prescribed distance, and all five developed symptoms of overuse injury during the follow-up.

Running-related injury

An injury was sustained by seven participants (12.5%) during the 4-week follow-up. Two participants were injured in the 3km intervention (6.9%). Five participants were injured in the 6km intervention (18.5%). The results of the time-to-event analysis are presented in Table 3 and Kaplan Meier plots of the injury-free proportion are presented with weeks and kilometers as timescale in Figure 2. Assuming a causal relationship, the number of obese novice runners who need to change from the 6km intervention to the 3km intervention to avoid one running-related injury (equivalent to numbers needed to treat) is six runners (based on the Intention-to-treat analysis with weeks as time scale).

Symptoms of overuse injury

Symptoms of overuse injury were observed in 21 participants (37.5%) during the follow-up. Eight participants reported symptoms in the 3km group (27.6%). Thirteen participants reported symptoms in the 6km group (48.1%). The results of the time to event analysis are presented in Table 3 and Kaplan Meier plots of the symptom-free proportion are presented with weeks and kilometers as timescale in Figure 2. The anatomical location, severity and proportion of symptoms in the 3km and 6km intervention groups during follow-up are presented in Table 4. Assuming a causal relationship, the number of

Figure 1. Flowchart and allocation of subjects.

obese novice runners who need to change from the 6km intervention to the 3km intervention to avoid symptoms (equivalent to numbers needed to treat) is seven runners (based on the intention-to-treat analysis with weeks as time scale).

DISCUSSION

This is the first randomized trial to provide insight into the start-to-run distance and the risk of running-related injury specifically among obese novice runners. A start-to-run distance of 6km per week

Table 2. Demographic characteristics of the participants randomized to the 3km and 6km intervention.

Participants randomized				
Characteristics	Unit/qualifier	Total (n=56)	3km (n=29)	6km (n=27)
Sex*	Female/Male	42/11 (79/21%)	23/6 (79/21%)	22/5 (81/19%)
Age†	Years	39.2 (±9.5)	38.3 (±10.2)	39.3 (±9.2)
BMI‡	Kg/m ²	32.7 (31.3, 34.3)	32.0 (31.2, 33.4)	33.3 (31.5, 34.6)
Activity level at home‡	Range 0-10§	3.6 (±1.4)	3.6 (±1.6)	3.7 (±1.3)
Activity level at work‡	Range 0-10§	3 (2, 5)	3 (2, 4)	3 (2, 5)
Participants with 0 training reported				
Characteristics	Unit/qualifier	Total (n=15)	3km (n=7)	6km (n=8)
Sex*	Female/Male	13/2 (87/13%)	6/1 (86/14%)	7 (87/13%)
Age†	Years	38.8 (±7.6)	34.7 (±8.2)	38.8 (±8.6)
BMI‡	Kg/m ²	32.2 (31.2, 34)	31.4 (31.2, 32.7)	32.4 (31.1, 34.3)
Activity level at home‡	Range 0-10§	3 (2.5, 4.5)	3 (2, 4)	3.5 (3, 5.5)
Activity level at work‡	Range 0-10§	4 (2, 7)	2 (1, 6)	4 (2.5, 7)

All participants randomized were included in the intention-to-treat analysis (n=56). A total of 15 participants reported no training sessions.

Abbreviations: BMI, Body mass index; SD, Standard deviation; Values are reported as: * Number (%), † means (SD) and ‡ Median (25th percentile, 75th percentile). § Numerical rank scale from 0 (sedentary) to 10 (highest possible activity level).

Table 3. CRD of injury and symptoms between the 3 km (n = 29) and 6 km (n = 27) intervention group week 2 and week 4 and after 10 km and 20 km.

Weeks as time scale									
	Analysis	Week 2				Week 4			
		Ref 6 km*	CRD†	95%CI	p value	Ref 6 km*	CRD†	95%CI	P value
Injury	ITT	17.8%	-14.5%	(-32.5;3.4)	0.11	26.8%	-16.3%	(-43.8;11.3)	0.25
	PP‡	22.5%	-22.3%	(-42.6;-2.0)	0.03	31.7%	-31.2%	(-57.0; -5.2)	0.02
Symptoms	ITT	58.0%	-37.6%	(-67.2; -7.9)	0.01	59.0%	-13.9%	(-50.3; 22.5)	0.46
	PP‡	71.0%	-59.3%	(-87.5;-31.0)	0.00	71.0%	-47.8%	(-81.0; -14.6)	0.01
Kilometers as time scale									
	Analysis	10km				20km			
		Ref 6 km*	CRD†	95%CI	P value	Ref 6 km*	CRD†	95%CI	P value
Injury	ITT	24.1%	-19.1%	(-42.7; 4.5)	0.11	30.9%	-25.7%	(-51.8; 0.5)	0.05
	PP‡	24.8%	-23.1%	(-46.7; 0.5)	0.05	31.9%	-29.2%	(-56.0; -2.4)	0.03
Symptoms	ITT	59.0%	-35.2%	(-65.7;-4.6)	0.02	73.2%	-34.0%	(-68.1; 0.1)	0.05
	PP‡	59.8%	-47.3%	(-76.2;-18.5)	0.00	74.9%	-50.5%	(-85.0; -15.9)	0.00

*Reference group was the runners randomized to the 6 km intervention. †Values are absolute percentage points (95% confidence interval). ‡ Participants were excluded if they uploaded no running sessions (3 km n=7; 6 km n=8) and right censored if their running exceeded 130% of the scheduled distance in a training session. Abbreviations: ITT= intention-to-treat; PP= Per-protocol; CRD, cumulative risk difference. A negative CRD indicates fewer injuries/symptoms (percentage point decrease in risk)

Figure 2. Injury-free proportion (y-axis) among runners allocated to the 3km and 6km intervention, visualized as a function of time scale (x-axis): (A) Weeks at Risk, (B) Distance, km. Symptom-free proportion (y-axis) in runners allocated to the 3km and 6km intervention, visualized as a function of time scale (x-axis): (C) Weeks at Risk, (D) Distance, km.

Table 4. Anatomical location, severity and proportion of symptoms in the 3km and 6km intervention groups during follow-up.

Program week	3km								6km							
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Location	Problem ^a				Substantial problem ^b				Problem ^a				Substantial problem ^b			
Foot	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Ankle	0	0	0	0	0	0	0	0	2	2	0	0	2	1	0	0
Front of lower leg	1	1	0	0	1	0	0	0	3	1	0	0	0	0	0	0
Back of lower leg	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0
Knee	0	0	1	1	0	0	0	0	1	2	2	0	0	0	1	0
Groin	1	0	0	0	0	0	0	0	1	1	0	0	1	1	0	0
Hip	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
Lower back	0	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Ankle and knee	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Groin and knee	0	0	0	0	0	0	0	0	1	0	1	1	0	0	0	0
Lower back and knee	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Proportion of participants ^c	3/29	2/17	3/13	1/9	1/29	0/17	0/13	0/9	11/27	7/13	3/9	2/8	4/27	2/13	1/9	0/8

^aProblem was defined as an Oslo Sports Trauma Research Center questionnaire (OSTRC) severity score above 0.

^bSubstantial problem was defined as a problem leading to moderate or severe reduction in training volume, or moderate or severe reduction in sports performance, or complete inability to participate in sport (OSTRC severity score of 13 or above in question 2 and/or question 3).

^cProportion of the uncensored participants with problem/substantial problem during follow-up

is common in running programs targeted novice runners. Nevertheless, the results of the present study indicate that a 6km per week start-to-run distance is associated with more running-related injuries compared to a more moderate distance of 3km per week. The cumulative risk of running-related injury was 26.8% with a start-to-run distance of 6km per week (3 x 2km per week and a 10% increase in distance the following 3 weeks) after four weeks of running. In comparison, the cumulative risk of running-related injury was only 10.5% with a start-to-run distance of 3km per week (3 x 1km per week and a 10% increase in distance the following 3 weeks) after four weeks of running. However, it should be emphasized that these results were affected by low compliance. Some participants completed much more running than prescribed and some never uploaded any training. In the supplementary per-protocol analysis, participants who ran excessively (130% of the prescribed distance in their program) were censored and participants who never uploaded any training were excluded. Based on the per-protocol analysis, the CRD of running-related injury was -31.2 % (95%CI: -57.0%; -5.2%, $p=0.02$) after four weeks of running. Furthermore, the CRD of overuse-injury symptoms was -47.8% (95%CI: -81.0%; -14.6%, $p=0.01$) after four weeks of running. These findings further support the supposition that obese novice runners need to be cautious in relation to their start-to-run distance and potential for running-related injury. Even a small difference seems to have a substantial impact on the risk of running-related injury the first four weeks of running (3km vs. 6km per week).

Only one other study has previously looked into the association between the start-to-run distance and running-related injuries among obese novice runners. The study was an observational 3-week prospective cohort study ($n=749$) based on the DANO-RUN study. In the DANO-RUN study, the CRD after 20km was -10.8% when the initial running distance the first week was ≤ 3 km compared with >6 km (reference).¹⁷ This is similar to the present study showing that obese novice runners reduce their injury risk substantially if the start-to-run distance is 3km instead of 6km per week. The considerably larger CRD after 20km found in the present study (-25.7%) compared

with the DANO-RUN may possibly be explained by the difference in study design. Plausibly, novice runners choose their start-to-run distance based on their susceptibility to injury, knowingly or unknowingly. In an observational prospective cohort study, such as the DANO-RUN study, this self-selection of the exposure could cause an overrepresentation of participants with specific characteristics associated with increased/decreased injury risk in one of the exposure groups. Most likely, the more injury-susceptible novice runners would select a shorter start-to-run distance and the less injury-susceptible novice runners a longer start-to-run distance. This source of bias is somewhat accommodated by the randomized design used in the present study. However, importantly, the results from the present study may still be biased because of the low compliance with the running programs. Essentially, the low compliance may cause a “self-selection issue” similar to that of the observational study design. Another explanation for the larger risk difference found in the present study is the running-related injury definition.²² In the present study, an injury was defined as a one-day training restriction or time-loss (reduced distance/intensity/frequency) whereas the definition in the DANO-RUN study was a seven-day training restriction or time-loss (reduced distance/intensity/frequency). Nevertheless, all injured participants in the present study were restricted more than seven days and could, therefore, have been classified as injured according to the DANO-RUN definition.

The substantial compliance problem in the present study illustrates the limitations in using training guidance as an injury prevention strategy. It doesn't work if the advice is ignored. Running-related injury in the 3km intervention group occurred only in participants who chose to run more than prescribed by the program. In addition, those who ran more than prescribed all developed symptoms of overuse injury. Therefore, the importance of motivating and educating obese novice runners to follow injury preventive training advice must be acknowledged. Future research, investigating how this is effectively achieved, is essential if injury preventive training guidance should have an effect. The Systems Theoretic Accident Mapping and Processes (STAMP) model is a promising tool in this endeavor and has

recently been adapted to a running-related injury context for distance runners in Australia.^{28,29} This model visualizes the complex system that includes control and feedback mechanisms between multiple hierarchical levels of determination, which can then be used to guide strategies for implementing novel injury prevention interventions.^{28,29} A similar model for running-related injury prevention in obese novice runners is not yet available.

Limitations of the study

The low compliance to the interventions must be acknowledged as a major limitation of the study. The intervention groups reported fewer completed training sessions than prescribed by the programs. The non-injured participants in the 3km and 6km group completed only 52% and 45% of the training session planned, respectively. Thus, the difference in the cumulative distance was lower than prescribed by the protocol. Consequently, the CRD found in the intention-to-treat analysis (CRD after four weeks = -16.3%, 95%CI: -43.8; 11.3, $p=0.25$) might have been underestimated compared with a scenario where all sessions were completed as prescribed. In addition, five participants in the 3km intervention ran longer distances than prescribed. As a result, they had almost comparable running exposure as had they followed the program received by the 6km intervention. Furthermore, seven of the participants in the 3km intervention and eight participants in the 6km intervention never uploaded any reports of running. Consequently, the difference in running exposure was less extreme than prescribed by the study-protocol. For this reason, the CRD might have been underestimated in the intention-to-treat analysis (CRD after four weeks = -16.3%, 95%CI: -43.8; 11.3, $p=0.25$) compared with a scenario where the training was completed as prescribed in the protocol.

Another major limitation that must be acknowledged is that five participants left the study without reporting a reason why (3km $n=4$, 6km $n=1$). This could potentially have biased the results dramatically if all had unreported running-related injuries. However, the four participants in the 3km intervention reported no symptoms the week before discontinuing the intervention, which suggests that injury was not the reason for leaving the study. The participant in the 6km intervention reported symptoms

the week before discontinuing the intervention (OSTRC Severity score = 31). The risk difference may have been underestimated if the participant in the 6km intervention left with an unreported running-related injury.

Finally, in the present study, the sample size was small. Consequently, the risk of a random difference between intervention groups was high. Nevertheless, Table 2 suggests that the intervention groups were equally distributed on the measured baseline characteristics. Still, other unobserved risk factors for running-related injury could have been unequally distributed. Another limitation of the small sample size is only seven running-related injuries occurred during the follow-up. The recommended minimum number of events per explanatory variable (EPV) is 10 in an analysis on CRD.³⁰ Ideally, 20 injuries were needed to meet the recommended minimum EPV. For this reason, caution is advised when interpreting the results of the analysis.

Other limitations of the study were the absence of blinding, absences of clinical assessment of injury, and the short follow-up period.

Generalizability

A large proportion of the population was women (42/56). This is in contrast to, a more equal distribution of men and women in previous studies.^{6,7} However, there is no consistent evidence that suggests women have different injury risk than men.³¹⁻³³

Only obese novice runners with no lower extremity injury the past two years were included in the present study. Obese novice runners with a more recent injury could potentially be at high risk of injury even when the start-to-run distance is 3km per week or less. In addition, only persons with less than one hour of sports activity experience per week were included. Obese novice runners with >one-hour sports experience per week from other activities might tolerate a start-to-run distance of more than 3km per week without substantial risk of injury.

In the present study, the distance was cumulated over three weekly running sessions. Imaginably, the risk of running-related injury could have been different if the weekly cumulative running distance had been distributed over more or fewer sessions

or the distance was unevenly distributed between sessions (e.g. 1km, 2km, 3km compared with 2km, 2km, 2km). Also, the “within session” cumulation of the running distance could have an influence on the risk of running-related injury. In the present study, the participants were instructed to run 500m as the shortest interval.

CONCLUSIONS

A 3km reduction from 6km per week to 3km per week in the start-to-run distance appears associated with fewer running-related injuries. Based on this, obese novice runners (BMI 30-35) are recommended a total start-to-run distance of ≤ 3 km the first week. Still, this advice should be used with caution. Importantly, sub-groups of obese novice runners could potentially have a high risk of running-related injury even with a start-to-run distance less than 3km per week (E.g. obese individuals with a previous injury). Conversely, other sub-groups may possibly tolerate a start-to-run distance of more than 6km per week while remaining at low risk of running-related injury (E.g. obese individuals with previous sports experience). Further studies are needed to address the appropriate start-to-run distance in sub-groups of obese novice runners.

REFERENCES

1. Hespanhol Junior LC, Pillay JD, van Mechelen W, et al. Meta-analyses of the effects of habitual running on indices of health in physically inactive adults. *Sports Med.* 2015;45(10):1455-1468.
2. Lee D, Pate RR, Lavie CJ, et al. Leisure-time running reduces all-cause and cardiovascular mortality risk. *J Am Coll Cardiol.* 2014;64(5):472-481.
3. Fields KB, Sykes JC, Walker KM, et al. Prevention of running injuries. *Curr Sports Med Rep.* 2010;9(3):176-182.
4. Videbaek S, Bueno AM, Nielsen RO, et al. Incidence of running-related injuries per 1000 h of running in different types of runners: A systematic review and meta-analysis. *Sports Med.* 2015;45(7):1017-1026.
5. van Gent RN, Siem D, van Middelkoop M, et al. Incidence and determinants of lower extremity running injuries in long distance runners: A systematic review. *Br J Sports Med.* 2007;41(8):469-480.
6. Buist I, Bredeweg SW, Lemmink KA, et al. Predictors of running-related injuries in novice runners enrolled in a systematic training program: A prospective cohort study. *Am J Sports Med.* 2010;38(2):273-280.
7. Kluitenberg B, van Middelkoop M, Smits DW, et al. The NLstart2run study: Incidence and risk factors of running-related injuries in novice runners. *Scand J Med Sci Sports.* 2015;25(5):e515-23.
8. Nielsen RO, Buist I, Parner ET, et al. Predictors of running-related injuries among 930 novice runners: A 1-year prospective follow-up study. *Orthop J Sports Med.* 2013;1(1):2325967113487316.
9. Smits DW, Huisstede B, Verhagen E, et al. Short-term absenteeism and health care utilization due to lower extremity injuries among novice runners: A prospective cohort study. *Clin J Sport Med.* 2016;26(6):502-509.
10. Koplan JP, Powell KE, Sikes RK, et al. An epidemiologic study of the benefits and risks of running. *JAMA.* 1982;248(23):3118-3121.
11. Nielsen RO, Ronnow L, Rasmussen S, et al. A prospective study on time to recovery in 254 injured novice runners. *PLoS One.* 2014;9(6):e99877.
12. Ristolainen L, Heinonen A, Turunen H, et al. Type of sport is related to injury profile: A study on cross country skiers, swimmers, long-distance runners and soccer players. A retrospective 12-month study. *Scand J Med Sci Sports.* 2010;20(3):384-393.
13. Bertelsen ML, Hulme A, Petersen J, et al. A framework for the etiology of running-related injuries. *Scand J Med Sci Sports.* 2017;27(11):1170-1180.
14. Malisoux L, Nielsen RO, Urhausen A, et al. A step towards understanding the mechanisms of running-related injuries. *J Sci Med Sport.* 2015;18(5):523-528.
15. Hreljac A. Etiology, prevention, and early intervention of overuse injuries in runners: A biomechanical perspective. *Phys Med Rehabil Clin N Am.* 2005;16(3):651-67, vi.
16. Martinez-Gonzalez MA, Varo JJ, Santos JL, et al. Prevalence of physical activity during leisure time in the european union. *Med Sci Sports Exerc.* 2001;33(7):1142-1146.
17. Nielsen RO, Bertelsen ML, Parner ET, et al. Running more than three kilometers during the first week of a running regimen may be associated with increased risk of injury in obese novice runners. *Int J Sports Phys Ther.* 2014;9(3):338-345.
18. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trials. *BMJ.* 2010;340:10.1136/bmj.c869.
19. Balady GJ, Chaitman B, Driscoll D, et al. American college of sports medicine position stand and american heart association. recommendations for cardiovascular screening, staffing, and emergency

-
- policies at health/fitness facilities. *Med Sci Sports Exerc.* 1998;30(6):1009-1018.
20. Dideriksen M, Soegaard C, Nielsen RO. Validity of self-reported running distance. *J Strength Cond Res.* 2016;30(6):1592-1596.
21. Nielsen RO, Cederholm P, Buist I, et al. Can GPS be used to detect deleterious progression in training volume among runners? *J Strength Cond Res.* 2013;27(6):1471-1478.
22. Kluitenberg B, van Middelkoop M, Verhagen E, et al. The impact of injury definition on injury surveillance in novice runners. *J Sci Med Sport.* 2016;19(6):470-475.
23. Clarsen B, Myklebust G, Bahr R. Development and validation of a new method for the registration of overuse injuries in sports injury epidemiology: The oslo sports trauma research centre (OSTRC) overuse injury questionnaire. *Br J Sports Med.* 2013;47(8):495-502.
24. Jorgensen JE, Rathleff CR, Rathleff MS, et al. Danish translation and validation of the oslo sports trauma research centre questionnaires on overuse injuries and health problems. *Scand J Med Sci Sports.* 2016;26(12):1391-1397.
25. Andersen CA, Clarsen B, Johansen TV, et al. High prevalence of overuse injury among iron-distance triathletes. *Br J Sports Med.* 2013;47(13):857-861.
26. Clarsen B, Bahr R, Heymans MW, et al. The prevalence and impact of overuse injuries in five norwegian sports: Application of a new surveillance method. *Scand J Med Sci Sports.* 2015;25(3):323-330.
27. Nielsen RO, Malisoux L, Moller M, et al. Shedding light on the etiology of sports injuries: A look behind the scenes of time-to-event analyses. *J Orthop Sports Phys Ther.* 2016;46(4):300-311.
28. Hulme A, Salmon PM, Nielsen RO, et al. From control to causation: Validating a complex systems model of running-related injury development and prevention. *Appl Ergon.* 2017;65:345-354.
29. Hulme A, Salmon PM, Nielsen RO, et al. Closing pandora's box: Adapting a systems ergonomics methodology for better understanding the ecological complexity underpinning the development and prevention of running-related injury. *Theoret Issues Ergonom Sci.* 2017;18(4):338-359.
30. Hansen SN, Andersen PK, Parner ET. Events per variable for risk differences and relative risks using pseudo-observations. *Lifetime Data Anal.* 2014;20(4):584-598.
31. van der Worp MP, ten Haaf DS, van Cingel R, et al. Injuries in runners; a systematic review on risk factors and sex differences. *PLoS One.* 2015;10(2):e0114937.
32. Hulme A, Nielsen RO, Timpka T, et al. Risk and protective factors for middle- and long-distance running-related injury. *Sports Med.* 2017;47(5):869-886.
33. Saragiotto BT, Yamato TP, Hespanhol Junior LC, et al. What are the main risk factors for running-related injuries? *Sports Med.* 2014;44(8):1153-1163.