

# Can running-related injuries be prevented through an online behavioural intervention in adult novice runners? Results of a randomised controlled trial

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## ABSTRACT

**Objective** To evaluate the effectiveness of the Runfitcheck on time until the onset of a new running-related injury (RRI) among adult novice runners.

**Methods** A three-arm randomised controlled trial was conducted over 7 months. Adult novice runners completed a baseline online questionnaire on their characteristics, running activity, RRIs and injury preventive behaviour. Runners were randomly allocated to one of two intervention groups or the control group (n=238). One intervention group obtained access to the Runfitcheck (n=252), an online intervention to encourage injury preventive behaviour, and was fortnightly promoted to use Runfitcheck; the other intervention group (n=251) was directed towards the Runfitcheck once. Runners were followed for 4 months, not all starting at the same time over 7 months. The main outcome measure was time to a new RRI using the Oslo Sports Trauma Research Centre Overuse Injury Questionnaire, and was analysed with survival analysis Cox regression. Generalised estimating equations (GEE) were used to gain insight into the effectiveness of the Runfitcheck.

**Results** The time to the occurrence of the first RRI did not differ between the study groups (Wald  $\chi^2=0.893$ ). GEE analysis showed no difference in the risk of a new RRI in the group that was referred to the Runfitcheck once (OR 1.22, 95% CI 0.86 to 1.74) nor in the active approach group (OR 1.01, 95% CI 0.71 to 1.45) compared with the control group. Furthermore, the onset of the new RRIs did not change over time (OR 0.96, 95% CI 0.91 to 1.01).

**Conclusions** The online intervention Runfitcheck was ineffective in reducing the instantaneous risk of new RRIs in adult novice runners. More research is needed to determine how injuries in novice runners can be prevented.

**Trial registration number** Dutch Trial Registry (ID: NL7823).

## BACKGROUND

In running, the injury risk is high. Experienced runners have an injury rate of 2.5–4 running-related injuries (RRI) per 1000 running hours,<sup>1 2</sup> and recreational runners have been shown to have an injury rate of six to eight RRIs per 1000 running hours.<sup>2 3</sup> In novice runners, the risk for injuries is the

### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The online intervention Runfitcheck is effective in encouraging preventive behaviour in novice runners.

### WHAT THIS STUDY ADDS

⇒ The online intervention Runfitcheck using the runner's profile for a tailor-made injury prevention programme was ineffective in reducing the chance of new running-related injuries in adult novice runners.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study showed that changing behaviour does not automatically lead to the prevention of injuries. It remains important to gain more insight and to do more research in preventing injuries in novice runners.

highest, ranging from 9 to 18 RRIs per 1000 running hours.<sup>1 2</sup> Despite the high injury risk, running is one of the most popular and fastest growing forms of physical activity worldwide.<sup>4</sup> Running is an easily accessible sport; you do not need much equipment to start and you can run at any time of the day at almost any place. Furthermore, running also has health benefits.<sup>5–7</sup> These are some reasons, among others, why it is also one of the most popular sports for starting to become physically active. In the Netherlands, 12.5% of the population participate in running, of which about 30% are novice runners.<sup>1</sup>

The popularity of the sport, in combination with the high injury risk, warrants good injury prevention interventions. To develop effective interventions for injury prevention insight in the risk factors for injuries is necessary. Previous studies showed several important risk factors for RRIs in (novice) runners,<sup>8–10</sup> such as lack of running experience.<sup>8 9</sup> Measures such as an individualised training programme, listening to signals from your body and favourable training behaviour (a graded training programme) seem important to prevent RRIs.<sup>10–12</sup> Novice



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runners, since being inexperienced runners, lack the experience to assess their training load accordingly<sup>8,9</sup> and should be more encouraged to implement injury preventive behaviour.

Therefore, interventions for preventing RRI in novice runners are important.<sup>8,9</sup> Although such interventions are limited, the studies available have shown their positive effect on behavioural aspects in runners.<sup>13,14</sup> Studies evaluating the effect of such online interventions on RRIs are limited as well.<sup>15,16</sup> One of the studies showed no effect of an online intervention programme on RRIs in recreational runners. It was proposed that this may be due to the intervention being too generic.<sup>16</sup> By contrast, the study by Hespanhol *et al*<sup>15</sup> showed a positive effect of online tailored injury prevention advice on RRIs in trail runners.

Given the high RRI risk in novice runners, there is a great interest in developing appropriate RRI preventive interventions in this population. Runfitcheck is a tailored online intervention (see online supplemental file 1), which promotes injury preventive behaviour and provides tools to runners to listen to their body's signals based on the load-taking capacity profile and running motivation of novice runners.<sup>17</sup> This intervention was found effective in encouraging preventive behaviour,<sup>14</sup> but the effectiveness of RRIs is unknown. Therefore, this study aimed to evaluate the effectiveness of the Runfitcheck on time until the onset of a new RRI among adult novice runners.

## METHODS

### Design and setting

To evaluate the effectiveness of Runfitcheck on RRIs, a three-arm randomised controlled trial with a follow-up of 4 months was conducted between October 2019 and April 2020.

### Participants, recruitment and randomisation

The inclusion criteria were: (1) to be 18 years or older and (2) considering themselves to be inexperienced, little experienced or somewhat experienced runners, or having less than 1 year of running experience. There were no criteria on the frequency or the distance they ran. From August 2019 to January 2020, runners were recruited via social media networks (Facebook, websites, Twitter, LinkedIn and newsletters) of the collaborating organisations (Dutch Consumer Safety Institute, Runner's World and Royal Dutch Athletics Association) or online registration for a running event of Le Champion (an event organiser for runners, cyclists and walkers in the Netherlands). Runners that applied for a running event of fewer than 10 km received a confirmation email with a short promotion for the study and a link to the study information, including an electronic consent form and the baseline questionnaire. The messages on social media contained the same information. Runners willing to participate gave their electronic informed consent and were included in the study.

After giving consent and filling out the baseline questionnaire (T0; online supplemental file 2), the runners were randomly allocated to one of the two intervention groups or the control group using a computerised random number generator (Research Randomizer, <https://www.randomizer.org/>). No restrictions were imposed to achieve a balance between groups in size or characteristics for the allocation, and simple randomisation was performed. Concealed allocation was used. All steps in the randomisation process were performed by one researcher (HvdD). Neither runners in the intervention groups nor researchers were blinded in this study.

### Patient and public involvement

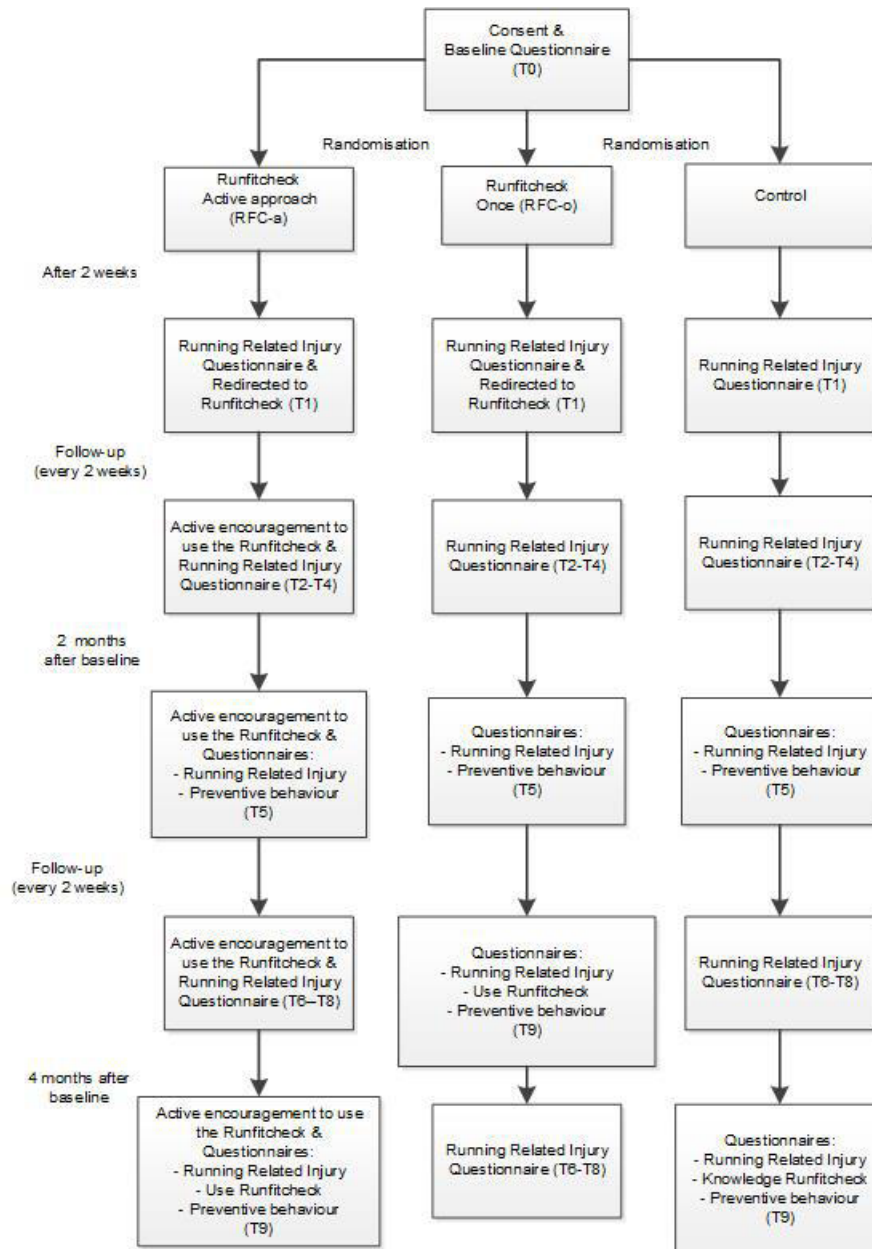
Runners were first involved in the study when developing the Runfitcheck intervention. They were also involved in evaluating the first version of the intervention. Novice runners and running experts suggested the content, and during its development, these two groups were involved in feedback sessions. The intervention is presented based on novice runners' wishes and needs. More detailed information on the development of the intervention is published elsewhere.<sup>15</sup> Previous research in novice runners was used as input for developing the research design, outcome measures and research question. The evaluation at the end of the study focused on the time spent on the intervention. The burden of the intervention was not discussed.

### The intervention

In this study, there were two intervention groups; one group was given access to the Runfitcheck through an active approach (RFC-a), and the other was referred to the Runfitcheck once (RFC-o). For a full description of the intervention, see online supplemental file 1. The RFC-a group was referred to the intervention every 2 weeks through the health monitor email, and the RFC-o was referred to the Runfitcheck just once in the first health monitor email. The control group was given no information regarding the Runfitcheck and continued running as usual.

### Outcome measures

The main outcome measure was time to a new RRI. An RRI was defined as any physical complaint sustained by a runner during running, resulting in the runner quitting the current running activity or not being able to start a new running activity,<sup>18,19</sup> including at least 1 day of time loss. To measure new RRIs, all groups received the Dutch version of the Oslo Sports Trauma Research Centre Questionnaire<sup>20,21</sup> every 2 weeks, in this study, referred to as the health monitor. The runners scored between 0 and 25 on each of the health monitor's four key questions (severity score), where 0 point meant no physical complaints. The maximum score for all the questions was 100 points. A score above 8 on the health monitor combined with at least 1 day of time loss was indicated as an RRI. The injury score was also used as an outcome



**Figure 1** Study design.

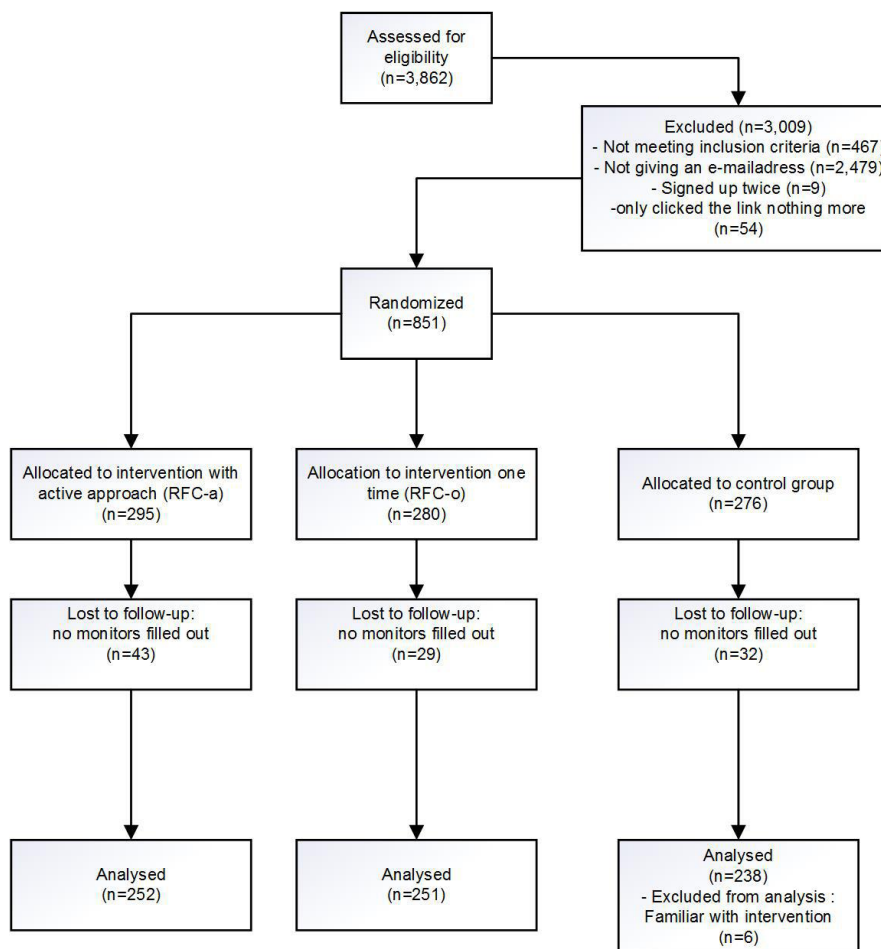
measure in this study for severity, with 8 being not severe and 100 being the most severe. The questionnaire (T1 through T9, [figure 1](#)) is designed and validated to register sports-related health problems, including acute and overuse injuries over time. It uses four key questions on the influence of physical complaints on running participation, training volume, running performance and to what degree physical complaints are experienced while running. Additional information on running exposure and exposure to other sports was collected. All questions referred to complaints and exposure in the preceding 2 weeks.

If the runner experienced minimal complaints, the questionnaire was finished by filling in a minimum score on these questions.<sup>21</sup> However, if the runner reported complaints that affected their ability to run,

the questionnaire continued by asking whether the complaint referred to an illness or injury. In the case of an injury, the runner was asked about the date the injury occurred, the nature of the injury and the body location (see online supplemental file 3). The number of time loss days (the total inability to run) was also registered. Subsequently, participants were asked if there had been another physical complaint in the last 2 weeks, for which they were asked the same questions as for the first injury. After these questions had been answered, the health monitor was finished.

### Procedures

At baseline, the runners were asked about their running experience, other sports activities, current injury/injuries, injury preventive behaviour and knowledge of



**Figure 2** Flow chart of the participants. RFC, Runfitcheck.

injury prevention in running (see online supplemental file 2). All groups received their first health monitor about 2 weeks after completing the baseline questionnaire. Runners in both intervention groups (RFC-a and RFC-o) received information about Runfitcheck by email and were redirected to the Runfitcheck website after completing the health monitor.

The control group also received an email with a link to the health monitor but did not receive information about the Runfitcheck. Additionally, they were only told that this was a study to get insight into injuries of adult novice runners. For the remainder of the study period, all groups received an email with a link to the health monitor every 2 weeks. In the accompanying email of the RFC-a group, they were stimulated to use the Runfitcheck by different calls to action and the email containing a link to the online intervention.

After 2 months and at the end of the study, all groups received a more elaborate questionnaire (T5 and T9, figure 1, online supplemental file 4). Participants were asked about injury preventive behaviour in the past 2 months. Finally, after 4 months, participants in both intervention groups were asked questions about their use and view of the Runfitcheck (T9, figure 1). Participants in the control group were asked whether they had heard about the Runfitcheck and whether they had used it or

not. The design study is presented in figure 1. Participants who completed at least six of the nine health monitors, including the last one, were entered into a draw offering a possibility to win either one of three running magazine subscriptions or one of three sports packages to the value of €50.

### Sample size

In this study, it was hypothesised that the use of Runfitcheck would lead to a reduction of 33% in RRI. The sample size calculation was based on calculations for longitudinal studies with repeated measures.<sup>22</sup> To achieve 80% power with a significance level of 0.05, taking into account eight repeated measures (every 2 weeks for 4 months) and a within-person correlation of 0.3,<sup>15</sup> the sample size calculation revealed that 98 participants per study group were needed in this study. Expecting a response rate of 70% and a loss to follow-up of 10%,<sup>15</sup> the sample size was estimated at 150 participants for each study group (a total of 450 participants).

### Data analysis

Descriptive characteristics were conducted for the baseline variables of the three groups. These baseline variables were analysed for differences between the groups using



**Table 1** Baseline characteristics of the runners (n=741)

Baseline characteristics	RFC-a (n=252)	RFC-o (n=251)	Control (n=238)	Total (n=741)
Age, years (%)				
18–24	5	8	8	7
25–34	25	25	26	26
35–44	33	27	22	28
45–54	25	27	27	27
55–64	9	9	15	11
65 or older	3	2	2	2
Gender (%)				
Male	34	34	30	33
Female	66	66	70	67
Height (cm), mean (SD)	174.0 (14.5)	174.4 (11.0)	173.9 (8.5)	174.1 (11.7)
Weight (kg), mean (SD)	73.0 (11.8)	73.0 (12.5)	71.0 (12.2)	72.4 (12.2)
Running experience, months (%)				
None, starting	<1	–	–	–
<6	6	5	5	6
6–12	11	9	14	11
13–18	10	10	11	10
19–24	11	12	13	12
>24	61	63	56	60
Running level (%)				
Inexperienced (novice)	6	7	7	7
Little experienced	31	30	30	30
Somewhat experienced	62	63	63	63
Experienced	–	–	–	–
Very experienced	–	–	–	–
Running frequency (%)				
Didn't start yet	1	1	2	2
Less than once a week	3	3	5	4
Once a week	11	13	13	12
Twice a week	37	38	34	36
Three times a week	42	39	39	40
Four or more times a week	5	6	7	6
Running minutes each time, mean (SD)	55.2 (31.9)	55.5 (32.4)	54.2 (31.2)	55.0 (31.8)
Injured at baseline (%)				
No	55	56	54	55
Yes, RRI	29	34	32	32
Yes, injury, different sport	15	9	13	12
No answer	1	1	1	1
Severity score baseline, mean (SD)	19.4 (27.1)	17.8 (25.8)	19.7 (26.7)	18.9 (26.5)

RFC-a, Runfitcheck through an active approach; RFC-o, Runfitcheck once; RRI, running-related injury.

the  $\chi^2$  test for the categorical variables and a one-way analysis of variance for the continuous variables.

Runners that only completed the baseline questionnaire and runners in the control group that used the Runfitcheck were excluded from analysis. To determine

if the missing data were random, the pattern of missing data was analysed in two ways.<sup>23</sup> First of all, it was assessed whether baseline variables (age, gender, running experience and running level) were associated with missing follow-up data by using univariate logistic regression.

**Table 2** Compliance with the study protocol, running exposure and RRI characteristics such as severity score and number of RRIs displayed per study group

	RFC-a (n=252)	RFC-o (n=251)	Control (n=238)
Compliance with the study protocol (%)			
Complete	30	31	30
Missing	25	25	17
Dropout	46	44	53
Running exposure			
Duration (min/2 weeks)*	52.9 (23.0)	51.8 (21.1)	53.3 (21.6)
Frequency (times/2 weeks)*	4 (2)	4 (2)	4 (3)
RRI characteristics			
RRI (n)	70	79	62
Injury rate†	13.1	15.3	12.6
Participants with new RRIs (%)	23	26	21
Time to new RRI (days)‡	40 (39)	41 (41)	36 (34)
Time loss (days/2 weeks)*	2.2 (1.6)	2.6 (2.4)	2.2 (1.9)
Total time loss (days)‡	8.9 (9.1)	9.0 (7.4)	7.7 (6.8)
Severity score, mean (SD)	63.1 (80.3)	69.5 (81.5)	64.3 (86.5)

\*Mean and SD over a 2-week period.  
†Injuries per 1000 running hours.  
‡Mean and SD over the total monitoring period.  
RFC-a, Runfitcheck through an active approach; RFC-o, Runfitcheck once; RRI, running-related injury.

Second, the outcome data of the health monitor were related to the outcome of the health monitor preceding and the one following to see whether these were related, also using univariate logistic regression.

Survival analysis Cox regression was used to assess the differences in time to new RRI between the three groups. Significance and the Wald statistic are reported, and the HR will be reported when significant. Generalised estimating equations (GEE) were used to gain insight into the difference in the risk of the occurrence of a new RRI and the development of the severity score between the three groups. Furthermore, GEE was used to see if there were changes over time (the monitor period) in the occurrence of new RRIs and/or the severity score and whether these differed between groups. The GEE accounts for the correlation of repeated outcome measures within subjects over time. Additionally, all these analyses were performed for the group runners who reported no injury at baseline and to analyse the effect of compliance to the Runfitcheck on RRIs and the severity score. These analyses are presented in online supplemental file 5.

All statistical analyses were performed using IBM SPSS (V.25), and significance was accepted at  $p < 0.05$ .

## RESULTS

In total, 3862 participants were interested in the study, of whom 851 were eligible for participation (figure 2). Of these eligible participants, 295 were randomly allocated to the intervention group with an active approach (RFC-a), 280 were allocated to the intervention group with the

one-off referral to the Runfitcheck (RFC-o) and 276 to the control group. Eighty-seven per cent of the participants ( $n=747$ ) completed at least one of the health monitors and were therefore included in the analyses. Six of the participants in the control group used the intervention (Runfitcheck) and were therefore excluded from the analysis, leaving 741 participants for further analysis. The complete flow of the participants can be found in figure 2.

Two-thirds (67%) of the runners were female; most were between 25 and 54 years old (table 1). Sixty per cent of the runners had more than 2 years of running experience, and a little over 60% assessed their running level as 'somewhat' experienced. Most runners ran twice or thrice a week, averaging 55 min (SD=31.8) per running session. At baseline, more than half of the runners (55%) had no (running-related) injury.

### Missing data

Univariate logistic regression revealed that most baseline variables were not statistically predictive of incomplete data. Only the analysis for gender showed that men were more likely to have missing data than women (OR 1.51, 95% CI 1.10 to 2.09,  $p < 0.05$ ). Non-response on one health monitor predicted non-response on the following health monitor. This assumes that the data are missing at random, which is accounted for in the GEE analysis.

### Compliance with the study protocol, running exposure and RRI characteristics

After 4 months of follow-up in all groups, about 30% completed all health monitors (100%), while about half

**Table 3** Effect of Runfitcheck on running-related injuries using generalised estimating equations

Group	RRI			Severity score		
	Beta	OR (95% CI)	P value	Beta	Wald $\chi^2$	P value
Control	Reference			Reference		
RFC-o	0.202	1.22 (0.86 to 1.74)	0.260	0.070	0.003	0.954
RFC-a	0.013	1.01 (0.71 to 1.45)	0.944	-0.432	0.123	0.725
Linear trend*	-0.040	0.96 (0.91 to 1.01)	0.121	-0.669	30.712	0.000

\*Adjusted for the intervention group.  
RFC-a, Runfitcheck through an active approach; RFC-o, Runfitcheck once; RRI, running-related injury.

of the participants dropped out during the monitor period (table 2). On average, a participant filled out six health monitors. There was no significant difference between groups in the number of health monitors filled out ( $F(2,738)=0.52$ ,  $p=0.60$ ).

A summary of running exposure and RRI characteristics is shown in table 2. Around 25% of the participants in the intervention groups reported a new RRI, and 20% in the control group (table 2). The injury rate ranged from 13.1 to 15.3 injuries per 1000 running hours. Time to new RRI ranged from 36 up to 41 days. The number of new RRIs did not significantly differ between groups ( $F(2,738)=0.61$ ,  $p=0.55$ ).

#### Effects of the intervention on RRI

Cox regression showed no differences in time to the first RRI between the study groups (Wald  $\chi^2=0.893$ ,  $p=0.640$ ).

The GEE analyses showed no difference between the study groups in the risk of a new RRI nor the severity score (table 3). During the monitoring period, there was no change in the development of RRIs overall and between groups. However, the linear trend for the severity score showed a significant decrease in the severity score over the monitor period for all participants together (table 3; linear trend).

In additional analyses, the same analyses were performed for the group runners who reported no injury at baseline. Furthermore, the effect of visiting the Runfitcheck on RRIs was analysed. These analyses showed no differences between groups (see online supplemental file 5).

## DISCUSSION

### Principal findings

In this study, we evaluated whether the Runfitcheck affected the time until the onset of a new RRI among adult novice runners. Based on our results, the Runfitcheck did not have a protective or harmful effect on the time until the onset of a new RRI. The time until the onset of the first new RRI did not differ between the study groups, and there was no effect of the Runfitcheck on the severity scores.

### Strengths and weaknesses in relation to other studies

In a previous study by Kemler *et al*, positive effects were found of the Runfitcheck on injury preventive behaviour of novice runners.<sup>14</sup> The assumption was made that increased injury preventive behaviour using the Runfitcheck would ultimately lead to a decrease in RRIs. However, this study did not demonstrate these positive effects to prevent RRI.

Fokkema *et al*<sup>16</sup> also showed no effect of an online intervention programme on RRIs in recreational runners. While Fokkema *et al* used a generalised intervention, in our study, we gave tailor-made advice based on running profiles rather than RRI. However, our approach was probably not specific enough to prevent RRIs. In contrast to the study of Fokkema *et al*<sup>16</sup> and our study, Hespanhol *et al*<sup>15</sup> did find a preventive effect of their tailor-made intervention. In their study, advice for recovery and prevention was given directly after notification of an RRI responding to the situation. This is a more 'right on time' way for (secondary) injury prevention since it is known most people take action the moment something happens and not before the onset of an injury.<sup>15 16</sup>

Looking at the running population in the other studies, Fokkema *et al*<sup>16</sup> included adult recreational runners who registered for one of three large running events between 5 and 42 195 km. Hespanhol *et al*<sup>15</sup> studied adult trail runners participating in a recent trail running event (15–62 km). Trail and recreational runners are probably more experienced runners, while in our study, the participants were expected to be mainly novice runners and probably less experienced runners. These may need a different approach when it comes to injury prevention. Novice runners have a high injury risk but lack a sense of urgency.<sup>24</sup> Fokkema *et al* and Hespanhol *et al* showed that runners with an RRI were more inclined to participate in the intervention than runners without physical complaints.<sup>15 16</sup> This was confirmed by the recent study of Verhagen *et al*,<sup>25</sup> which showed that recreational runners do not have a conscious will to prevent injuries and use self-regulation to deal with complaints and injury. When runners do not have any experience with being injured, they might not feel the urge to protect



themselves against injury. Future research in injury prevention for recreational/novice runners should consider this.

Another point of discussion is the definition of the experience level of runners, namely novice, recreational and competitive runners. There is no clear definition in the literature, and every study uses different definitions, making a comparison of research outcomes and drawing conclusions difficult.<sup>26 27</sup> By reporting the injury incidence in relation to the amount of time spent running, a comparison would be possible; however, relatively few studies report this.<sup>26</sup> Hence, in consultation with the Royal Dutch Athletics Association, we based the definition mainly on the runners' feelings. However, to make research outcomes more comparable, an international consensus on the definition and/or the way of reporting the experience level of runners must be reached. This would also translate to better practical application by the running community, coaches, physical therapists, etc.<sup>27</sup>

In this study, an RRI was defined as any physical complaint sustained by a runner during running, resulting in the runner quitting the current running activity or not being able to start a new one,<sup>18 19</sup> including at least 1 day of time loss. This definition may have missed some RRIs, such as runners with iliotibial band (ITB) syndrome, achilles tendinopathy and patellafemoral pain (PFP) syndrome (common RRIs). Runners with these injuries rarely quit their current running activity or cannot start a new running activity (including at least 1 day of time loss). The definition used in a study impacted the outcome of the study. For comparability of future studies, consensus on definitions of runners and RRI is of major importance.

One of the strengths of the study is how the intervention is presented. This is based on the wishes and needs of novice runners. Therefore, theoretically, the Runfitcheck is expected to be attractive and stimulating enough for novice runners. However, the results show poor compliance with the Runfitcheck in both intervention groups (see online supplemental file 5). Further research could consider using the theory of planned behaviour (TPB) in evaluating the Runfitcheck since this theory may explain half of the variance around RRI preventive behaviour and intention.<sup>28</sup>

Finally, the dropout rate in this study was relatively high (48%) compared with other studies.<sup>16 29</sup> However, just 13% of all the participants were excluded from the analysis. When the runners completed at least one health monitor, data until they dropped out were included in the analysis. The dropout rate could (probably partly) be explained by runners with an injury (temporarily) quitting running and dropping out of our study, reflected in the significant decrease in the number of new RRIs per health monitor over the research period. Previous research has also shown that an injury is one of the main reasons to quit being active.<sup>29</sup>

## Meaning of the study and future research

Using a tailor-made intervention based on a runner's profile was ineffective in preventing RRIs in novice runners. Even though this study included just one group of mainly novice runners, it suggests that preventive research and creating awareness concerning injury is difficult when dealing with novice runners. As suggested before, the TPB could be used in future studies when evaluating Runfitcheck. The TPB might explain the variance around RRI preventive behaviour and intention and may give starting points to create awareness concerning injuries in more novice/less experienced runners.

The components of the Runfitcheck are developed in cooperation with several (running) experts. These components could be investigated concerning their effect on RRI individually. For example, the preventive effects of strength exercises can be studied, and proven effects can be used to prevent RRIs in novice runners. Coaches may be able to use the individual exercises in their training programme for novice/less experienced runners.

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**Contributors** EK was guarantor and together with HvdD responsible for the conceptualisation of the idea of the study, data analysis, interpretation of the data and preparation of the manuscript. EK and VG acquired funding. VG, EK and HvdD designed the study. EK and HvdD prepared the materials and implemented the study. HvdD collected the data and carried out the data analyses. HvdD drafted the manuscript with contribution from EK. VG was responsible for the critical review of the manuscript. All authors read and approved the final manuscript.

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**Ethics approval** This study involves human participants and was approved by the Medical Ethics Review Committee of the Amsterdam University Medical Centers, location Academic Medical Center (W19\_241#19.290, Amsterdam, the Netherlands). Participants gave informed consent to participate in the study before taking part.

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**Data availability statement** Data are available upon reasonable request. The relevant anonymised patient-level data set analysed during the current study is available from the corresponding author on reasonable request.

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