# Pre-race medical screening and education reduce medical encounters in distance road races: SAFER VIII study in 153 208 race starters

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#### **Abstract:**

**Objectives:** To examine the efficacy and feasibility of an online pre-race medical screening and educational intervention program for reducing medical complications in long distance races.

**Methods:** This was an 8-year observational study of medical encounter rates among 153 208 Two Oceans race starters (21.1km and 56km) in South Africa. After the first 4-year control (CON) period, we introduced an online pre-race medical screening (based on European pre-exercise screening guidelines) and an automated educational intervention program. We compared the incidence of medical encounters (per 1000 starters; all and serious life-threatening) in the CON vs. the 4-year intervention (INT) period.

**Results:** In comparison to the CON period (2008-2011: 65 865 starters), the INT period (2012-2015: 87 343 starters) had a significantly lower incidence (adjusted for age group, sex, race distance) of all medical encounters by 29% [CON=8.6 (7.9-9.4); INT=6.1 (5.6-6.7), p<0.0001], in the 21.1km race by19% [CON=5.1 (4.4-5.9); INT=4.1 (3.6-4.8), p=0.0356], and in the 56km race by 39% [CON=14.6 (13.1-16.3); INT=9.0 (7.9-10.1), p<0.0001]. Serious life-threatening encounters were significantly reduced by 64% [CON=0.6 (0.5-0.9); INT=0.2 (0.1-0.4); p=0.0003) (adjusted for age group and sex). Registration numbers increased in the INT period (CON=81345; INT=106743) and overall % race starters were similar in the CON vs. INT period. WBGT was similar in the CON and INT periods.

**Conclusion:** All medical encounters and serious life-threatening encounters were significantly lower after the introduction of a pre-screening and educational intervention program, and the program was feasible.

#### Introduction

Regular physical activity (PA) is an important lifestyle intervention for primary and secondary prevention of non-communicable disease [1-5]. The recommended minimum weekly healthy "dose" of exercise is 150 minutes at moderate to vigorous intensity. [5-7] Mass community-based sports events such as distance running events have, over the last 2-3 decades, seen substantial growth in participant numbers,[8] with a notable increase in older participants (<a href="http://www.runningusa.org/annual-reports">http://www.runningusa.org/annual-reports</a>). While regular PA has numerous health benefits, PA is associated with medical encounters [9] [10], including acute myocardial infarction and sudden death [11-16]. The reported absolute risk of sudden death during marathons, and similar races, varies between 0.004 to 0.033 per 1000 race entrants [17-21] [22, 23]. The incidence of other non-cardiac, but serious life-threatening medical encounters during running is not well-studied [22-28], but is about 0.5 per 1000 race entrants (0.17 to 1.55 per 1000 race entrants) [22, 23, 28].

To reduce the risk of acute medical complications during sport, pre-competition medical evaluation has been proposed, with the main focus on younger elite athletes [14, 29-32] [33]. However, the older exercising population has a higher incidence of acute medical complications during exercise [34] and a number of international organizations developed consensus recommendations for pre-participation screening of master athletes [35] [36] [37] or middle-aged/senior individuals wishing to engaging in leisure-time sports (European Association for Cardiovascular Prevention and Rehabilitation - EACPR) [29]. We recently reported that using the EACPR guidelines, >30% runners would require a full medical assessment before race participation - mainly linked to runners reporting musculoskeletal conditions. We therefore suggested a revision of these guidelines and proposed that pre-race screening be considered to identify runners with a "very high", "high" and "intermediate risk" for medical complications during exercise [38]. We are not aware of any studies investigating the efficacy of pre-participation medical screening to reduce acute medical encounters in athletes who engage in leisure-time sports such as mass community-based distance running events.

Therefore, the primary aim of this study was to determine the efficacy of an online preparticipation screening and educational intervention program to reduce the incidence of acute medical encounters, including serious life-threatening encounters and deaths, at distance running events. Secondary aims were to: a) explore whether the screening and intervention strategy could be easily or conveniently performed (feasibility), b) examine if extrinsic factors such as environmental stress could account for variation in medical encounters rather than the pre-screening, and c) determine if the intervention program altered the race entrant risk profile.

# Methods

### Study design

We conducted an observational study over 8 years with a 4-year initial control (CON) period (2008-2011) and a subsequent 4-year intervention (INT) period (2012-2015).

# Participants and data collection

The Two Oceans Marathon races are mass community-based running events in South Africa and comprise of a 21.1km and a 56km race. Entries to the 21.1km race are open to novice runners and require no qualifying time, while entry for the 56km race requires a sub-5 hour 42.2km-qualifying time. Entrants, defined as any runner registering for the races (typically open 3-5 months before the races), for both races over an 8-year period (2008-2015) were considered as participants. In each of the 8 years of the study (control and intervention) race entrant data (demographics including age, sex, previous participation, and previously completed races) and race-day data (number of starters and finishers) were obtained, with permission, from the race organizers. Demographic and race data are in the public domain and are obtainable from the race website.

In each year of the study (control and intervention periods), we obtained the de-identified data on medical encounters in runners who presented to the medical facilities on race day, with permission, from the race medical team and the race organizers. Medical facilities consisted of on-route medical stations and a medical facility at the finish. For the purposes of this study, a medical encounter was defined as "any runner who required medical care on race day that was severe enough to warrant a medical assessment by a doctor, either in the medical facility at the end of the race, on route at the medical stations, or at one of the referral hospitals (for runners that were assessed by medical staff on the route)". Minor medical encounters (not requiring an assessment by a medical doctor) were not included in

our study. A serious life-threatening medical encounter was defined as "a medical encounter that could result in death unless urgently diagnosed and treated, specifically encounters that resulted in either admission to a high-care (intensive care and observation) medical area at the event, or transport (with or without admission) to a hospital". An event related sudden death was defined as "a medical encounter that resulted in sudden death, where the medical problem resulting in death was deemed to be directly related to the event, and the onset of the medical problem occurred during the event or within 24 hours of the finish time". Race physicians recorded accurate and detailed clinical information of each medical encounter in a standardized format.

The Research Ethics Committee of the University of Cape Town (REC 009/2011 and REC R030/2013) approved the protocol and the Research Ethics Committee of the University of Pretoria (REC 433/2015) approved the on-going data collection, and subsequent analysis of the data.

# Intervention period - online pre-race medical screening, risk stratification and educational intervention

In the intervention period (2012 to 2015), we introduced a compulsory online pre-race medical screening questionnaire or "self-assessment of risk", based on the EACPR guidelines [29, 39]. The questionnaire consisted of the following main categories of medical history: cardiovascular disease (CVD), symptoms of CVD, risk factors for CVD, other chronic disease (respiratory disease, metabolic or hormonal disease, gastrointestinal disease, nervous system disease, renal or bladder disease, hematological or immune system disease, cancer, allergies), general prescription medication use, medication use during racing, and a past history of collapse during racing (Supplementary Appendix Table S1). Algorithms were developed to risk stratify runners into one of four risk categories (Supplementary Appendix Table S2), based on the EACPR guidelines [29, 39]. Risk stratification was performed on completion of the online screening process, in an automated fashion and runners completing the screening were given the opportunity to consent that their data could be used for research purposes.

#### **Educational intervention program**

In conjunction with the online pre-race medical screening questionnaire, an educational intervention program was developed to educate runners, via automated email, on the potential medical complications that may occur during moderate- to high-intensity exercise (Supplementary Appendix Table S3). Educational material was delivered to runners in the two highest risk categories ("very high risk" and "high risk") by personalized email and they were specifically advised to seek clearance from their medical practitioner. In addition, we conducted a general educational intervention to all runners through weekly posts on a dedicated medical section of the official race website, and regular email notification to all runners to visit the race website. No runner was prevented from race participation by the race organizers or the race medical team. The final decision to run on race day was left to the runner and his/her medical practitioner.

# Primary outcome measures to assess efficacy

*Incidence of race-day medical encounters* 

The incidence of all medical encounters, serious life-threatening medical encounters and deaths were the main outcome measures to assess efficacy of the intervention. The incidence was calculated as the number of runners with medical encounters or deaths per 1000 race starters. The main analysis was by observation period (control: 2008-2011; intervention: 2012-2015), with further analysis of the incidence in sub-groups by race distance (21.1km or 56km race).

# Secondary outcome measures

a. Race entrant numbers, did-not-start (DNS) rate, and the did-not-finish (DNF) rate

For the purposes of this study, we used additional main outcomes to address possible concerns of race organizers that the screening and intervention program may reduce race entry numbers, or increase dropout after race entry by reducing number of race starters:

• Number of race entrants were defined as the number of runners registered for the races (typically 3-5 months before the races). The rationale for this outcome measure is that

- race organizers may express a possible concern that by implementing the intervention, it may negatively affect race entries.
- Race starters were defined as race entrants who started the race and we report the didnot-start (DNS) rate (% entrants who did not start the race). The runners who started, but did not finish the race is reported as did-not-finish (DNF) rate (%). The rationale for these outcome measures is to address a potential concern that the intervention may result in a greater % race entrants not starting or finishing the race.

# b. Influence of environmental stress on medical encounter rates

We collected data on environmental conditions (hourly from 6 AM to 12 PM) on race day of each year (temperature, humidity, rainfall, cloud cover, and wind speed) from the database of the South African Weather Services (with permission). We used the Wet Bulb Globe Temperature (WBGT) Index (calculated using Wet Bulb Globe Temperature (°C), humidity, time of day and cloud cover data) as the main outcome variable to assess if environmental stress affected medical encounter rates.

# c. Risk profile of race starters changed in the intervention

In the INT period, 87343 runners started the race, and 76654 runners (87.8% of starters) gave consent that their medical information (risk category data) could be used for research purposes. Data on the % race starters in each risk category (Supplementary Appendix Table S3) was only available in the INT period. The DNS in the INT period was used as an outcome variable to determine if the risk profile of race starters changed in the 4-year intervention period.

# Statistical analysis of data

All analysis was done using the SAS (V9.4) statistical analysis system. Modified Poisson regression models, using a robust error estimator (log link function) to estimate the incidence rates (IRs) and CIs, were used to analyze all medical outcomes. The correlated structure of the data, due to the same athletes taking part in several of the races over the 8-year study period, was accounted for by using an unstructured correlation matrix. Data is provided to show the number of unique athletes in the control and intervention periods.

The estimate of the prevalence risk and 95%CI for the CON and INT period were reported and the estimated relative risk (RR) was reported as a measure of the intervention effect.

Models compared outcomes CON and INT, reporting prevalence risks and 95%CIs.

Models for any medical encounters included the individual years, and contrasted CON (2008-2011) versus INT (2012-2015) years to obtain RRs and 95%CIs. Models for serious life-threatening/death medical encounters included an indicator for CON and INT to obtain RRs and 95%CIs.

Unadjusted model results for medical encounters are reported in the Supplementary Appendix. Adjusted models included possible confounders of race distance, sex, and age category to adjust the intervention estimates. The interaction term for race distance and year was included to obtain separate estimates for the two race distances.

The possible influence of environmental stress on the association between medical encounters and the intervention was assessed by including wind speed and WBGT index as a confounder in the final model.

For the comparison of risk categories for chronic illness, the "very high risk" and "high risk" categories were combined and the "intermediate risk" and "low risk" categories were combined in a model that was adjusted for age category, sex, and race distance.

#### **Results**

# Study population and overall race starter demographics

Over the 8-year study period, a total of 87 525 unique runners were studied: 26 753 runners who only took part in the CON period, 38 719 who only took part in the INT period and 22 053 runners who took part in both periods. In the 8-year study period, there were 188 088 race entrants and 153 208 race starters (81.5%). Demographic details of all race starters in the control and intervention period is available in the Supplementary Appendix (Table S4). The study population for the CON and INT period included 92 038 male starters (CON = 41 026; INT = 51 012) and 61 170 female starters (CON = 24 839; INT = 36 331).

#### **Incidence of medical encounters (CON vs. INT period)**

#### All medical encounters

The unadjusted (crude) incidence of all medical encounters are available in the Supplementary Appendix (Table S5). The adjusted (age category, sex) incidence (per 1000 race starters) of all medical encounters in all runners (p < 0.0001), 21.1km runners (p = 0.0356) and 56km runners (p < 0.0001) was significantly lower in the intervention period - a 29% reduction in all runners, and a 19% and a 39% reduction in the 21.1km and 56km runners respectively (Table 1).

Table 1: The adjusted (by age category and sex) incidence (per 1000 runners starting the race: 95% CI) and Relative Risk of all medical encounters in the CON vs. INT period, and by year and race distance

|        | CON period |         |        |         |         | INT period |        |        |        |         | RR                 |
|--------|------------|---------|--------|---------|---------|------------|--------|--------|--------|---------|--------------------|
|        | 2008       | 2009    | 2010   | 2011    | All CON | 2012       | 2013   | 2014   | 2015   | All INT | (CON<br>vs INT)    |
| 21.1km | 4.87       | 3.98    | 4.98   | 6.98    | 5.09    | 2.21       | 4.89   | 6.16   | 4.42   | 4.14    | 0.81               |
|        | (3.66;     | (2.95;  | (3.75; | (5.50;  | (4.42;  | (1.54;     | (3.86; | (4.95; | (3.44; | (3.60;  | (0.67;             |
|        | 6.47)      | 5.38)   | 6.61)  | 8.87)   | 5.87)   | 3.17)      | 6.20)  | 7.67)  | 5.69)  | 4.76)   | 0.99) <sup>a</sup> |
| 56km   | 12.51      | 18.60   | 11.95  | 16.41   | 14.62   | 10.47      | 7.91   | 11.75  | 6.63   | 8.96    | 0.61               |
|        | (9.87;     | (15.31; | (9.66; | (13.42; | (13.08; | (8.38;     | (6.16; | (9.56; | (5.12; | (7.93;  | (0.52;             |
|        | 15.85)     | 22.61)  | 14.79) | 20.06)  | 16.34)  | 13.07)     | 10.16) | 14.46) | 8.60)  | 10.13)  | 0.72) <sup>b</sup> |
| All    | 7.80       | 8.61    | 7.71   | 10.70   | 8.63    | 4.81       | 6.22   | 8.51   | 5.42   | 6.09    | 0.71               |
|        | (6.48;     | (7.20;  | (6.47; | (9.16;  | (7.89;  | (3.89;     | (5.24; | (7.33; | (4.52; | (5.56;  | (0.62;             |
|        | 9.40)      | 10.30)  | 9.20)  | 12.51)  | 9.44)   | 5.94)      | 7.39)  | 9.89)  | 6.49)  | 6.68)   | 0.80) <sup>a</sup> |

RR: Relative Risk

<sup>a</sup>: p < 0.0001; <sup>b</sup>: p = 0.0356; <sup>c</sup>: p < 0.0001

The number needed to treat (NNT) statistic of the screening and educational intervention to prevent one medical encounter is 394 for all runners, 1053 for 21.1km runners and 177 for 56km runners.

Serious life-threatening (including death) medical encounters

There were only 39 and 19 serious life-threatening (including death) medical encounters respectively in the CON and INT periods, therefore data for the years 2008-2011 and 2012-2015 were combined for the analysis. The unadjusted (crude) incidences of serious life-threatening (including death) medical encounters are available in the Supplementary Appendix (Table S6).

In the adjusted analysis (for age category and sex) incidence of serious life-threatening medical encounter data was analyzed for the two race distances separately and combined. In the intervention period, the adjusted incidence (per 1000 runners; 95% CI) of serious life-threatening (including death) medical encounters were reduced significantly in all (p = 0.0003) and 21.1km runners (p = 0.0014) (Table 2).

Table 2: The adjusted (by age category and sex) incidence (per 1000 runners starting the race: 95% CI) and Relative Risk of serious (life threatening / death) medical encounters in the control vs. intervention period, and by race type

|        | CON period    | INT period    | RR (CON vs. INT)              |
|--------|---------------|---------------|-------------------------------|
| 21.1km | 0.5 (0.4-0.8) | 0.2 (0.1-0.3) | 0.26 (0.12-0.60) <sup>b</sup> |
| 56km   | 0.7 (0.5-1.1) | 0.3 (0.1-0.5) | 0.48 (0.22-1.05) °            |
| All    | 0.6 (0.5-0.9) | 0.2 (0.1-0.4) | 0.36 (0.21-0.62) <sup>a</sup> |

RR: Relative Risk; a: p = 0.0003; b: p = 0.0014; c: p = 0.0666

In 56km runners there was a trend for a reduction in serious life-threatening (including death) medical encounters (p = 0.0666). In total, in the intervention period, there was 64% reduction in the risk of a serious life-threatening (including death) medical encounter in all runners, with a 74% and 52% reduction in the risk in for 21.1km and 56km runners respectively.

The number needed to treat (NNT) statistic of the screening and educational intervention to prevent one serious (life threatening / death) medical event was 2670 (for all runners) (unadjusted data).

# Race entrants, did-not-start (DNS) rate, and did-not-finish (DNF) rate

The number of race entrants, race starters and finishers, and the percentage (%) of race entrants that Did-Not-Start (DNS) the race, or Did-Not-Finish (DNF) the race in the CON vs. INT period is shown in Table 3. The number of race entrants increased by 31% from the CONT to the INT period. DNS and DNF rates were similar in the pre- and post-intervention period.

Table 3: The number of race entrants, the number of race starters and finishers, and the proportion (%) of race entrants that Did-Not-Start (DNS), and Did-Not-Finish (DNF) the race in the CON vs. INT period

|           | All runners | CON period | INT period |
|-----------|-------------|------------|------------|
| Entrants  | 188088      | 81345      | 106743     |
| Starters  | 153208      | 65865      | 87343      |
| DNS (%)   | 18.5        | 19.0       | 18.2       |
| Finishers | 150177      | 64420      | 85757      |
| DNF (%)   | 2.0         | 2.2        | 1.8        |

#### **Environmental stress and medical encounter rates**

The environmental conditions on race day for each year, and in the CON and INT periods are shown in Table 4.

Table 4: Environmental conditions on race day for each year, and in the control (2008-2011) and intervention periods (2012-2015). Values are means (95% CI) of 7 hourly values from 06h00 to 12h00 on race day

|           | CON period |        |        |        |           | INT period |        |        |        |                   | P-<br>Value # |
|-----------|------------|--------|--------|--------|-----------|------------|--------|--------|--------|-------------------|---------------|
|           | 2008       | 2009   | 2010   | 2011   | All CON   | 2012       | 2013   | 2014   | 2015   | All INT           |               |
| Wind      | 144        | 148    | 153    | 116    | 140 (116- | 231        | 141    | 143    | 149    | 166 (141-<br>191) | 0.1431        |
| direction | (98-       | (101-  | (106-  | (70-   | 165)      | (184-      | (94-   | (96-   | (102-  |                   |               |
| (deg)     | 191)       | 194)   | 200)   | 163)   | 105)      | 277)       | 187)   | 189)   | 195)   | 191)              |               |
| Wind      | 9.6        | 7.8    | 3.5    | 1.5    | 5.6 (4.9- | 6.9        | 13.1   | 9.6    | 6.6    | 9.0 (8.4-<br>9.7) | < 0.0001      |
| speed     | (8.2-      | (6.4-  | (2.1-  | (0.1-  | 6.2)      | (5.5-      | (11.7- | (8.2-  | (5.3-  |                   |               |
| (knots)   | 10.9)      | 9.1)   | 4.8)   | 2.9)   | 0.2)      | 8.3)       | 14.5)  | 10.9)  | 8.0)   | 9.1)              |               |
| WBGT      | 16.5       | 15.4   | 15.2   | 13.5   | 15.1      | 12.1       | 18.4   | 15.1   | 13.4   | 14.7(13.7-        |               |
| index*    | (15.1-     | (14.0- | (13.8- | (12.1- | (14.1-    | (10.7-     | (17.0- | (13.7- | (13.7- | 15.8)             | 0.5289        |
| muex.     | 17.8)      | 16.8)  | 16.5)  | 14.9)  | 16.2)     | 13.5)      | 19.7)  | 16.5)  | 14.8)  | 15.0)             |               |

<sup>\*:</sup> Wet Bulb Globe Temperature (WBGT) Index – calculated using temperature (°C), humidity, time of day and cloud cover data #: p value CON period vs. INT period

The means of the calculated Wet Bulb Globe Temperature (WBGT) index over the 8-year period ranged from a minimum of 12.1 to 18.4. There was no significant difference in the WBGT index between the CON vs. the INT period (p=0.5289). The average wind direction (degrees) was not significantly different in the INT period vs. CON period (p=0.1431). However, the average wind speed (knots) was significantly higher in the INT period vs. CON period (p<0.0001). There was no correlation between either WBGT index (p=0.4927) or wind speed (p=0.7558) and the incidence of all medical encounters over the 8-year study period (Supplementary material – Figure S1).

Finally, the effect of environmental stress on the association between medical encounters and the intervention was also assessed by including wind speed and WBGT index as a

confounder in the final model on incidence rates of all medical encounters. This adjustment of the intervention effect for environmental stress resulted in no significant change to the relative risk (RR=0.75; 95%CI: 0.62-0.91) for all medical encounters.

# Race starter risk profile in the INT period

The observed number and % race starters in the INT period (consenting race starters; n= 76654) in each risk category (determined by chronic illness and risk factors for chronic illness), by year and race distance in the post-intervention period are depicted in Table 5.

Table 5: Race starters (21.1km, 56km and all (n and %) in each risk category in the INT period

| Race distance | Risk<br>category | 2012        | 2013        | 2014        | 2015        | All INT      |
|---------------|------------------|-------------|-------------|-------------|-------------|--------------|
| 21.1km        | Very high        | 364 (3.4)   | 344 (3.1)   | 363 (2.9)   | 356 (2.8)   | 1427 (3.0)   |
|               | High             | 1480 (13.7) | 1199 (10.6) | 1319 (10.6) | 1330 (10.6) | 5328 (11.3)  |
|               | Intermediate     | 4877 (45.2) | 4290 (38.0) | 4865 (39.2) | 4870 (38.7) | 18902 (40.2) |
|               | Low              | 4065 (37.7) | 5453 (48.3) | 5876 (47.3) | 6018 (47.9) | 21412 (45.5) |
| 56km          | Very high        | 174 (3.5)   | 272 (3.4)   | 231 (3.0)   | 257 (2.9)   | 934 (3.2)    |
|               | High             | 639 (12.8)  | 862 (10.9)  | 802 (10.2)  | 798 (9.0)   | 3101 (10.5)  |
|               | Intermediate     | 2861 (57.3) | 4171 (52.9) | 4207 (53.5) | 4541 (51.4) | 15780 (53.3) |
|               | Low              | 1318 (26.4) | 2587 (32.8) | 2620 (33.3) | 3245 (36.7) | 9770 (33.0)  |
| All runners   | Very high        | 538 (3.4)   | 616 (3.2)   | 594 (2.9)   | 613 (2.9)   | 2361 (3.1)   |
|               | High             | 2119 (13.4) | 2061 (10.8) | 2121 (10.5) | 2128 (9.9)  | 8429 (11.0)  |
|               | Intermediate     | 7738 (49.1) | 8461 (44.1) | 9072 (44.7) | 9411 (44.0) | 34682 (45.2) |
|               | Low              | 5383 (34.1) | 8040 (41.9) | 8496 (41.9) | 9263 (43.2) | 31182 (40.7) |

The percentage of "very high-risk" and "high-risk" race starters in the 4-year INT period were 3.1% and 11.0% respectively, and these were similar in the 21.1km and 56km runners (Table 5). There was a significant decrease in the combined percentage of "very high risk" and "high risk" race starters in over the 4-year period (2012 = 16.8%; 2013 = 14.0%; 2014 = 13.4%; 2015 12.8%) (p<0.0001) (adjusted for age category, sex, and race distance).

# **Discussion**

It is well established that the risk of a medical encounter (including sudden death) during prolonged moderate- to high-intensity exercise is related to extrinsic factors (environmental stress [40-42], race distance [23]) and intrinsic factors (older age [8, 13, 43], males [8, 13]). Underlying chronic disease including risk factors for chronic disease are recognized as risk factors associated with medical complications during moderate- to

high-intensity exercise. Therefore, international medical associations have produced consensus-based recommendations/guidelines to screen individuals prior to engaging in moderate- to high-intensity exercise [29, 35-37, 39]. To our knowledge, this is the first study investigating the efficacy of a pre-race medical screening and educational intervention program, to reduce the incidence of all medical encounters in recreational distance runners participating in a mass community-based sports event. In only one other recent study, a pre-race educational intervention program was implemented to reduce the risk of exercise associated collapse in runners [44]. Our main finding is that a pre-race screening and educational intervention was associated with a significant reduction in medical encounters (by 29%), particularly serious life-threatening medical encounters (by 64%). We also show that our observed reductions in medical encounter rates could not be accounted for by known risk factors for medical encounters such as age, sex, race distance, and environmental conditions. We also present some data that our intervention program did not negatively affect overall number of race entrants.

In 2008, we initiated studies to reduce the risk of an adverse medical event during exercise: the **SAFER** (**S**trategies to reduce **A**dverse medical events **F**or the **E**xercise**R**) studies [23, 45-47]. In the first of these studies, we recorded a high incidence of sudden cardiac death and other serious life-threatening medical complications in runners over a 4-year period (2008 -2011) [23]. We concluded that it should be a priority to reduce these medical encounters. Therefore, from 2012, we introduced pre-race medical screening, as proposed by the EACPR [29], with an educational intervention program at running events. As far as we are aware, this observational study, with a 4-year control and a 4-year intervention period, is the first to show promising results that a pre-race medical screening and educational intervention can reduce acute medical encounters in master and leisure athletes that participate in mass community-based distance running events.

In this study, we carefully considered other risk factors that may account for variations in medical encounter rates, including age, sex, race distance and environmental stress. We adjusted all incidence rates for age and sex, and report data separately for two the race distances (21.1km and 56km). We show that the incidence of medical encounters was highest in the longer 56km race, and this is consistent with previous findings [23]. However, we also show that the incidence of medical encounters in the intervention period

was significantly reduced in both races, particularly serious life-threatening medical encounters.

We are aware that environmental stress (specifically the WBGT) has been associated with increased risk of medical encounters at endurance sports events [40, 41], and there are international guidelines for modification or cancellation of sports events, based on the WBGT [42]. Therefore, we carefully considered whether environmental stress (specifically the WBGT index), could account for our observed reduction in medical encounters in the intervention period. Our results show that the WBGT over the 8-year period was not related to the incidence of medical encounters, and we attribute this observation to two main factors: the relatively small variation in the WBGT index over the 8-year study period, and that WBGT values were consistently in the "low to moderate" risk for the entire 8-year period [40]. We note that the highest WBGT value was recorded in the intervention period (2013). Our data therefore show that environmental conditions did not account for our observed reduction in medical encounters following the intervention.

We also recognized that the feasibility of implementing pre-participation medical screening is a key aspect for potential wider application. It should be simple, pragmatic, not introduce barriers to participation, and not be counter-productive to the public health message of the benefits of regular exercise. A potential threat, largely expressed by race organizers, is that a pre-race screening program would negatively affect race entry numbers and/or result in fewer entrants starting the race. Other concerns could be that runners would have a negative attitude towards the pre-race screening process, and that the cost to a health care system would increase significantly.

Our results show that the number of race entrants was not reduced in the post-intervention period; rather, there was a 31% growth in race entrants. The percentage of overall entrants not starting the race was similar in the CON and INT periods. Most runners (>70%) gave consent that their pre-race medical data could be used for research, and the % consenting runners increased over the 4–year period from 62% in 2012 to 78.4% in 2015, perhaps indicating that runners did not view the screening and education negatively. We believe the data indicate that pre-race medical screening and education did not negatively impact race participation, and the majority of the runners support research endeavors to improve race safety.

We did not specifically study the potential cost implication of runners that were advised to undergo medical clearance before participation. However, only about 14% of race entrants were in the two higher risk categories, and we advised them to seek medical clearance. Most of these runners are under the care of medical practitioners, and undergo routine medical assessments for these conditions. Our educational intervention encouraged these runners to discuss the medical considerations when participating in endurance running events with their physician. We suggest that, for these runners, this should not add a cost burden to the health care system. The exception would be a small number of runners who reported only symptoms suggestive of CVD. This would result in a new consultation with a medical practitioner, and be an additional cost to the health care system. However, this has to be balanced with the cost saving associated with any reduction in medical encounters during exercise.

We do not have any data on the risk profile (chronic illness and risk factors for chronic illness) of race entrants in the 4-year control period. These data have never been reported, and we could not obtain these data without informing race entrants of increased risk of a medical complication during exercise, as this would have important ethical implications. However, we could study the effects of the intervention program on altering the risk profile of race starters, but only in the 4-year intervention period. We were encouraged by the observation that there was a significant reduction in the % "very high risk" or "high risk" race starters over the 4-year intervention, and we note that the largest reduction was after the first year in the intervention period.

The strengths of this study are the large number of runners studied over an 8-year period, the accurate and consistent documentation of the medical encounters, that we adjusted medical encounter rates for risk factors such as age, sex and race distance, and that we show that environmental stress, specifically WBGT index, did not account for our observed reduction in medical encounters. This study has several limitations. Firstly, this was not a randomized-controlled trial, but rather a pragmatic field study, and we therefore cannot conclude that the reduction in the incidence of medical encounters was only as a result of our intervention. Secondly, we acknowledge that the intervention consisted of multiple components including screening and risk stratification, combined with an individually targeted educational intervention for "very high risk" and "high risk" subgroups and a general educational intervention for all runners. Therefore, any effect of our

intervention cannot be attributed to a single component of the intervention. Thirdly, we relied on self-reported data from runners. Fourthly, we acknowledge that we do not have data on the individual runner risk profile (chronic illness and risk factors) in the control period and therefore we cannot show that the risk "profile" of runners differed in the control and intervention periods. Finally, we also do not report any data to show that runners complied with the advice to seek medical clearance, but we did collect information on how many runners sought medical clearance in the period 2013-2015. Larger studies, including more endurance events and thus more serious medical encounters, are needed, to confirm the results of the present study.

In summary, our study shows promising results that following the introduction of an online pre-race medical screening and educational intervention program at a mass community-based running event, we observed a reduction in all medical encounters, mainly in longer races, and serious-life-threatening medical encounters, mainly in the shorter race. In addition, the screening and intervention program was easily accomplished, and appears to alter the race starter risk profile. Therefore, a pre-race screening and educational intervention has the potential to change current practice worldwide and we suggest that race organizers and race medical teams may consider implementing such programs to improve race safety.

# What are the new findings?

- An online pre-race medical screening and educational intervention program may significantly reduce medical encounters and alter race starter risk profile
- It is feasible to implement an online pre-race medical screening and educational intervention program at a mass community-based running event
- The results of this study have the potential to change current practice of providing medical care at mass community-based endurance sports events worldwide
- Race organizers and race medical teams may consider implementing such programs to improve race safety

# Impact on clinical practice in the near future

- Race medical directors and race organizers may consider implementing an online prerace medical screening and educational intervention program at mass community-based endurance events
- Race medical directors and race organizers can document the impact of implementing such programs
- Implementation of pre-race medical screening and education could lead to improved race safety
- The results of this study have the potential to change policy

# **Contributorship:**

Martin Schwellnus (MS): responsible for the overall content as the study and database guarantor, study concept, study planning, data collection, data interpretation, manuscript (first draft), manuscript editing, facilitating funding

Sonja Swanevelder (SS): study planning, data analysis including statistical analysis, data interpretation, manuscript editing

Esme Jordaan (EJ): study planning, data analysis including statistical analysis, data interpretation, manuscript editing

Wayne Derman (WD): study planning, data collection, data interpretation, manuscript editing

Mats Borjesson (MB): data interpretation, manuscript editing

Karen Schwabe (KS): study planning, data collection, data interpretation, manuscript editing

#### **Data sharing statement:**

No additional data are available

# **Competing Interests:**

The authors declare that there are no competing interests

# **Funding statement:**

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#### Patient involvement

No, Participants were not involved with the planning of the study. Results of the study will be disseminated to participants through race organizer websites.

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