



# The effect of small versus large clog size on emergency response time: A randomized controlled trial

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## ARTICLE INFO

Available online xxxx

### Keywords:

Covid-19  
Clog size  
Intensive care medicine  
Rapid response team  
Clinical trials as topic

## ABSTRACT

**Objectives:** To assess the effect on healthcare professional emergency response time and safety of small compared to large clog size.

**Design:** Randomized controlled trial.

**Setting:** The intensive care unit of a single university medical centre in The Netherlands.

**Participants:** Intensive care medicine professionals.

**Interventions:** Participants were randomized to wear European size 38 clogs (US male size 6½, US female size 7½) or European size 47 clogs (US male size 13½, US female size 14½) clogs and were required to run a 125 m course from the coffee break room to the elevator providing access to the emergency department.

**Main outcome measures:** The primary outcome was the time to complete the running course. Height, shoe size, self-described fitness, age and staff category were investigated as possible effect modifiers. Secondary endpoints were reported clog comfort and suspected unexpected clog-related adverse events (SUCRAEs).

**Results:** 50 participants were randomized (25 to European size 38 clogs and 25 to size 47 clogs). Mean age was 37 years (SD 12) and 29 participants (58%) were female. The primary outcome was 4.4 s (95% CI −7.1; −1.6) faster in the size 5 clogs group compared to the size 12 clogs group. This effect was not modified by any of the predefined participant characteristics. No differences were found in reported clog comfort or SUCRAEs.

**Conclusions:** European size 38 clogs lead to faster emergency response times than size 47 clogs.

**Trial registration:** NCT04406220

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## 1. Introduction

Good clogs are essential for professionals in intensive care medicine. They should provide adequate foot protection, be easy to clean and allow for comfortable walking as well as fast running. The latter is pivotal to reach emergency situations as quickly as reasonably possible to prevent patients from popping their clogs prematurely.

Many hospitals, including ours, provide clogs free of charge. While colour is standardized to white, the clever clogs in the executive board of our hospital have left the choice of size to the individual healthcare professional. In fact, a very wide range of clog sizes is provided, ranging from European sizes 32 to 49 (US male size 1½ to 15, US female size 2½ to 16). This has led to substantial practice variation when it comes to clog size selection. This is likely based on personal size preferences and physiologic considerations rather than solid scientific evidence relating clog size to running speed. As a result, at least some patients may now be deprived of optimal care.

In this context, it is important to point out that the current world record on the 100 m sprint was run in European size 47½ (US male size 14, US female size 15) footwear, lending credibility to the hypothesis that larger clog sizes may cause better performance [1]. However, this has not been subjected to the rigour of a randomized controlled trial, which may come as a surprise in this era of evidence-based medicine. To fill this pressing knowledge gap, we therefore decided to compare two clog sizes in the target population of professionals in intensive care medicine with running speed as a primary outcome measure.

## 2. Methods

This was a parallel two-group randomized controlled trial carried out at the department of intensive care medicine at Amsterdam UMC, VUmc site, Amsterdam, The Netherlands. Eligible participants were healthcare professionals aged 18 years or older who were willing and able to run on clogs. Enrolled participants provided informed consent.

Participants were randomized to wear European size 38 clogs (US male size 6½, US female size 7½) or European size 47 clogs (US male size 13½, US female size 14½). Randomization was done online in randomly permuted blocks stratified by gender (hosted by CastorEDC,

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Amsterdam, The Netherlands). Participants were required to run a course of 125 m (137 yards) from the coffee break room to the elevator providing access to the emergency department (Fig. 1). To mimic clinical circumstances, participants were instructed to assume a relaxed sitting position upon which they were summoned to unexpectedly start running towards the elevator. Along the course, participants encountered existing obstacles including one door that needed manually opening and three sets of doors that use motion sensors to open automatically and three 90 degree turns.

The primary endpoint was the time to complete the running course. Secondary endpoints were reported clog comfort and suspected unexpected clog-related adverse events (SUCRAEs). Gender, age, height, shoe size, self-described fitness and staff function were recorded as possible effect modifiers. We estimated that the enrolment of 50 subjects would provide 80% power to show a 5-s difference in the response time at an average response time of 30 s with a 6-s standard deviation.

The mean between-group difference in the primary endpoint was estimated using a linear model. As recommended, the primary analysis was adjusted for the stratification variable by including gender as a covariate in the linear model [2,3]. Model residuals were normally distributed. Evidence for effect modification by participant characteristics was analysed by adding to the main model a dummy variable for each characteristic and an interaction term between the characteristic and the randomization group (main effect). Reported clog comfort was compared with the Cochran-Armitage test for trend. The number of adverse events was compared using Fisher's exact test. The trial data are made available as online supplementary material.

3. Results

Fifty-six eligible healthcare professionals were invited to participate. Six of them refused consent, one claiming a clogged-up nose, five for lack of motivation. Fifty participants were randomized, 25 to European size 38 clogs and 25 to European size 47 clogs. The baseline characteristics of the randomized participants are shown in Table 1.

The primary outcome was completed in a mean time of 34.2 s (SD 4.9) in the European clog size 38 group compared to 38.8 s (SD 6.4) in the European clog size 47 group, an estimated stratification-adjusted difference of -4.4 s (95% CI -7.1; -1.6). The main effect was not modified by any of the predefined participant characteristics (Fig. 2).

For the predefined secondary outcomes, we found no differences in reported clog comfort or adverse events (Table 2). A total of 10 SUCRAEs occurred in 8 healthcare professionals. In the European clog size 38

Table 1  
Baseline characteristics of participants.

	European size 38 clogs (n = 25)	European size 47 clogs (n = 25)
Male (%)	10 (40.0)	11 (44.0)
Mean age, years (SD)	36 (12)	38 (12)
Mean height, cm (SD)	176 (10)	176 (10)
Median shoe size (IQR)	40 (IQR 38; 44)	40 (IQR 38; 43)
Self-described level of fitness (%)		
Less fit than usual for age	1 (4.0)	1 (4.0)
Average fitness for age	13 (52.0)	10 (40.0)
Fitter than usual for age	11 (44.0)	14 (56.0)
Staff function		
Nurse	11 (44)	10 (40)
Physician	11 (44)	13 (52)
Other	3 (12)	2 (8)

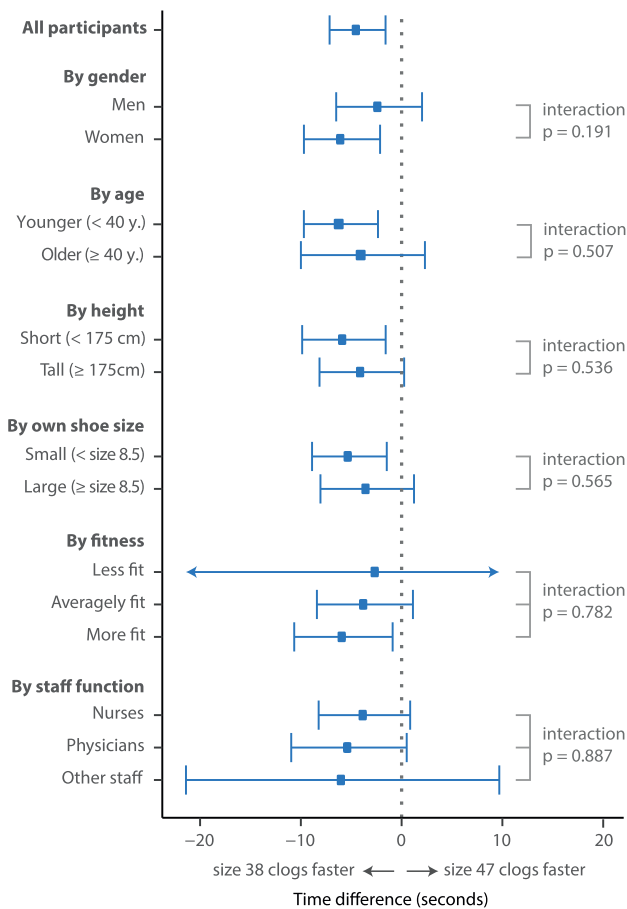


Fig. 1. Impressions of the conduct of the study, clog sizes, and an example of a suspected unexpected clog-related adverse event (SUCRAE).



Fig. 2. Difference in mean time to complete a running course on European size 38 clogs compared to European size 47 clogs for all 50 participants (the study primary outcome) and for predefined subgroups. Participants randomized to European size 38 clogs were faster than those randomized to European size 47 clogs. There were no interactions between any of the subgroups and the main effect, indicating that we found no evidence of effect modification.

**Table 2**  
Secondary endpoints.

	European size 38 clogs (n = 25)	European size 47 clogs (n = 25)	Difference
Reported clog comfort			p-value for trend difference .2081
Uncomfortable (%)	14 (56)	19 (76)	
Average comfortable (%)	10 (40)	5 (20)	
Very comfortable (%)	1 (4)	1 (4)	
Participants with a one or more adverse events (%)	5 (20)	3 (12)	Odds ratio 1.4 (95%CI 0.31; 13.2)

**Table 3**  
The clog size study continues a long tradition of trials investigating a low versus high strategy in intensive care medicine. Low is usually better.

Study	Subject	Low arm	High arm	Result
Hebert (1999) [4]	Transfusion Trigger	7 g/dL	10 g/dL	Low better
Villanueva (2013) [5]	Transfusion Strategies for Acute Upper Gastrointestinal Bleeding	7 g/dL	9 g/dL	Low better
Holst (2014) [6]	Transfusion Requirements in Septic Shock	7 g/dL	9 g/dL	No difference
ARDS network (2000) [7]	Tidal volume in ARDS	6 mL/kg	12 mL/kg	Low better
Van den Berghe (2001) [8]	Glucose control	80–110 mg/dL	<215 mg/dL	Low better
NICE-SUGAR (2009) [9]	Glucose control	81–108 mg/dL	<180 mg/dL	High better
Bernard (2002) [10]	Induced hypothermia after cardiac arrest	33 °C	37 °C	Low better
Nielsen (2013) [11]	Targeted Temperature Management after cardiac arrest	33 °C	36 °C	No difference
Asfar (2014) [12]	Mean arterial pressure in septic shock	65–70 mmHg	80–85 mmHg	No difference
Elbers (2020, this study)	Clog size	European size 38	European size 47	Low better

group, reported adverse events were pain during running (3x), lost pocket items (2x) and a bruised toe. In the European clog size 47 group, reported adverse events were lost pocket items (2x), a coiffure calamity and a bleeding finger (possibly from aggressive pushing of the elevator call button at the finish line).

The original raw data is available from [www.amsterdam.medicaldatascience.nl](http://www.amsterdam.medicaldatascience.nl).

#### 4. Discussion

This is the first randomized controlled trial to investigate the effect of clog size on emergency response times by intensive care professionals. We found that participants randomized to European size 38 clogs were able to arrive on the scene of a medical emergency faster than participants randomized to European size 47 clogs.

There was no indication of effect modification by gender, age, height, own shoe size, self-reported fitness or staff function. We found no differences in reported clog comfort or the number of adverse events.

The clog size study continues a long tradition of randomized controlled trials in intensive care medicine comparing low and high strategies for treatment [4–12]. As shown in Table 3, these trials have often concluded that lower values are better. This study is in line with that general trend.

These findings have important implications for healthcare professionals and hospital administrators. Intensive care professionals should wear European size 38 clogs rather than European size 47 clogs. This should lead to a novel clog related 'best practice' standard for hospital accreditation agencies. If the present results can be replicated in a multicentre study, inclusion in international guideline recommendations should be deemed appropriate. From the perspective of healthcare cost reduction, it seems reasonable for hospital purchasing departments to only procure European size 38 clogs, likely at a substantial quantity discount.

The randomized controlled trial is widely regarded as the cornerstone of evidence based medicine. However, the very large number of null result trials in intensive care medicine have fuelled the discussion on their usefulness. Some have even suggested that physiological reasoning might be useful to better inform healthcare professionals and clinical trials. And the advent of artificial intelligence and machine learning have prompted some to advocate personalized medicine. This

trial might turn these worrisome tides as our analyses clearly revealed an effect that contradicts physiological reasoning, calls for personalized approaches, anecdotal observations and expert opinion. Thus, despite popular belief, the choice of clog size should not be matched to foot size for intensive care professionals. Further studies are clearly needed to compare other sizes of clogs with European size 38, that will serve as the new gold standard given the results of our study.

We acknowledge the slight chance that this trial suffered from practice misalignment [13]. The trial protocol disturbed the normal relation between the exposure (clog size) and its determinant characteristics (perhaps most importantly, foot size). Both the intervention and the comparator arms did not represent clinical practice outside of the trial.

This design facilitates trial efficiency as it increases treatment contrast as well as the probability of detecting an effect and should therefore be recommended. The increased treatment contrast does come at the cost of limited generalizability. Reassuringly, this design is common in major randomized controlled trials. In fact all trials in Table 3 may serve as excellent examples.

Our regional ethics committee declared that our protocol did not require formal approval as they thought our study failed to qualify as scientific research. Obviously we disagree with this position and we should like to add that luckily none of the other trials in Table 3 were judged by this ethics committee, as they might have concluded that these trials would equally have failed to qualify as scientific research.

Finally, it is important to point out that this study is completely unrelated to covid-19, the societal burden of which may leave us from clogs to clogs in three generations, so that this may be used as a key word to increase the likelihood of expeditious publication. As the Dutch would say: "now breaks my clog!" [14]

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