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*A pilot RCT with 510 participants*

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## Spraino reduces incidence rate and severity of lateral ankle sprain injuries in indoor sports:

### *A pilot RCT with 510 participants*

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### Introduction

Lateral ankle sprains (LAS) are the most common injury in sports. They are especially prevalent in indoor sports, where high shoe-surface friction is considered a risk factor for “*non-contact*” injuries. Spraino<sup>®</sup> is a novel product that minimizes friction on the lateral edge of the shoe, thereby potentially mitigating the risk.

### Materials and Methods

We designed and conducted an outcome-assessor-blinded, parallel-group, two-arm pilot RCT (NCT03311490). 510 sub-elite indoor sport athletes with a history of LAS injuries were randomly allocated (1:1) to Spraino<sup>®</sup> or to a “*do-as-usual*” control group. The allocation procedure was concealed to investigators and participants. Match and training exposure, LAS injuries and time-loss data were captured via weekly text messages. Specifically, the objective was to determine preliminary effect (rate and severity) and safety (harms) of Spraino<sup>®</sup> when used to prevent LAS injuries among indoor sport athletes.

### Results

480 participants completed the trial, reporting a total of 151 LAS injuries. 96 were categorized as non-contact, of which 34 were severe. Incidence rate ratios of 0.87 (95% CI, 0.62-1.23) for all LAS injuries, 0.64 (95% CI, 0.42-0.97) for non-contact LAS injuries, and 0.41 (95% CI, 0.19-0.89) for severe non-contact LAS injuries were computed; all outcomes favoured Spraino<sup>®</sup>. The time-loss ratio for the total number of injuries was 0.65 (95% CI, 0.45-0.93). Six participants reported minor harm related to slipping because of Spraino<sup>®</sup>.

### Conclusion

Spraino<sup>®</sup> was associated with a lower rate of non-contact LAS injury, lower time-loss, and with few reports of harms. Findings should be replicated in a confirmatory RCT.

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