












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Does the Spraino low-friction shoe patch prevent lateral ankle sprain injury in indoor sports? A pilot randomised controlled trial with 510 participants with previous ankle injuries

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ABSTRACT

Background Lateral ankle sprains are common in indoor sports. High shoe–surface friction is considered a risk factor for non-contact lateral ankle sprains. Spraino is a novel low-friction patch that can be attached to the outside of sports shoes to minimise friction at the lateral edge, which could mitigate the risk of such injury. We aimed to determine preliminary effectiveness (incidence rate and severity) and safety (harms) of Spraino to prevent lateral ankle sprains among indoor sport athletes.

Methods In this exploratory, parallel-group, two-arm pilot randomised controlled trial, 510 subelite indoor sport athletes with a previous lateral ankle sprain were randomly allocated (1:1) to Spraino or ‘do-as-usual’. Allocation was concealed and the trial was outcome assessor blinded. Match and training exposure, number of injuries and associated time loss were captured weekly via text messages. Information on harms, fear-of-injury and ankle pain was also documented.

Results 480 participants completed the trial. They reported a total of 151 lateral ankle sprains, of which 96 were categorised as non-contact, and 50 as severe. All outcomes favoured Spraino with incidence rate ratios of 0.87 (95% CI 0.62 to 1.23) for all lateral ankle sprains; 0.64 (95% CI 0.42 to 0.98) for non-contact lateral ankle sprains; and 0.47 (95% CI 0.25 to 0.88) for severe lateral ankle sprains. Time loss per injury was also lower in the Spraino group (1.8 vs 2.8 weeks, $p=0.014$). Six participants reported minor harms because of Spraino.

Conclusion Compared with usual care, athletes allocated to Spraino had a lower risk of lateral ankle sprains and less time loss, with only few reported minor harms.

Trial registration number NCT03311490.

INTRODUCTION

A 2014 systematic review on incidence and prevalence of lateral ankle sprain injuries identified indoor sports as ‘high risk’ sports, reporting a pooled injury incidence rate of 7 sprains per 1000 exposures.¹ This conspicuously high incidence rate was highlighted in an evidence review from the International Ankle Consortium,² as well as in a 2018 clinical guideline.³

High friction between shoe and surface is a posited risk factor for non-contact lower limb injuries across various sports,^{4–7} and shoe–surface friction is generally high in indoor sports.⁵ The majority of lateral ankle sprains occur via a ‘non-contact’ injury mechanism,^{1,2,8} in which the shoe is only in contact with the floor, indicating that high shoe–surface friction is an important part of the injury mechanism.

Spraino is a new low-friction patch (figure 1) designed to prevent these ‘friction-related’ sprains in indoor sports by minimising friction at the lateral edge of the shoe sole and thus removes the anchoring point between shoe and floor, around which non-contact lateral ankle sprains typically occur.⁹ Removing that anchor reorients the vector of the ground reaction force (figure 2) allows the foot to realign more easily and prevents the rapid excessive inversion and internal rotation associated with lateral ankle sprains¹⁰ (online supplementary video). The first natural step following promising laboratory testing is to establish ‘proof-of-principle’,¹¹ preliminary evidence of effectiveness, on clinically relevant endpoints. At present, it is unknown how Spraino might affect important clinical outcomes.

Therefore, the aims of this exploratory pilot trial were to determine preliminary effectiveness and safety of using Spraino to prevent lateral ankle sprains among subelite indoor sport athletes with a previous lateral ankle sprain, when compared with a ‘do-as-usual’ control group.

METHODS

Design

We designed and conducted a two-arm, parallel-group, exploratory pilot randomised controlled trial to assess proof-of-principle for Spraino, being preliminary effectiveness and safety in lateral ankle sprain injury prevention among high risk indoor sport athletes. Participants were randomly allocated (1:1) to an intervention (Spraino) group or a control (do-as-usual) group. The trial was registered at ClinicalTrials.gov (NCT03311490) on 17 October 2017 and enrolment was conducted between 19 October 2017 and 28 February 2018. The trial protocol (online supplementary appendix



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Figure 1 Indoor sports shoe with Spraino low-friction patches attached on the outside.

S6) was developed using the PREPARE trial guide¹² and Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist.¹³ We report the trial using the Consolidated Standards of Reporting Trials (CONSORT) 2010 extension for pilot and feasibility trials.¹⁴

Participants

Participants were recruited from 91 indoor sports teams (handball, basketball and badminton) competing at divisional or league level in Denmark. Participants were eligible for inclusion if they: (1) were aged 18 years or older; (2) could read, speak and understand Danish; (3) could receive and reply to text messages using Short Message Services (SMS); (4) performed indoor sport in a subelite level team with at least 2 weekly practice sessions; (5) had incurred at least one lateral ankle sprain in the preceding



Figure 2 Preventive mechanism of Spraino: in case of a bad landing, Spraino minimises the otherwise high shoe–surface friction at the lateral edge of the shoe. This minimises the horizontal ground reaction forces (GRFs), thereby bringing the GRF vector closer towards the joint centre which serves to prevent excessive ankle inversion and internal rotation.

24 months; and (6) had returned to play at the commencement of our trial.

We included athletes with a previous lateral ankle sprain as they are at particularly ‘high risk’ of new injury,^{15 16} making injury risk mitigation pertinent. At the time of recruitment, all athletes were participating fully in their sport and reported no acute injury symptoms.

Sample size

The sample size was determined by the formula $n = 4/T (\sqrt{\theta_0} - \sqrt{\theta_1})^2$ where n is the number of participants in each arm, T the observation time, and θ_0 and θ_1 the incidence rates in the control and intervention group.¹⁷ We anticipated an incidence rate of 4.9 ankle sprains per 1000 hours of exposure¹ without Spraino, and an incidence rate of 2.94 per 1000 hours in participants randomised to Spraino (40% lower). With a power of 80% and an α of 5%, an exposure time of ~15 350 hours would be needed in each arm. Assuming an average exposure of 3 hours of court activities per week per participant (including off-season), 250 participants would be needed to be observed for 20 weeks. Assuming a dropout rate of 15%, the 250 participants should be observed for at least 23 weeks.

Randomisation

Randomisation was performed after the included participants had provided written consent and the completed baseline questionnaires had been collected. We generated the two comparison groups using balanced block randomisation. The random component in the sequence generation process was a drawing of lots. Block sizes were determined by the number of enrolled participants within a given team, with an equal amount of lots representing allocation for intervention and control being used to assure a 1:1 allocation ratio (ie, if a team had 9 enrolled players, then 10 lots, 5 representing each group (intervention and control), were included). The lots (wooden beads) were identical in appearance and drawn from an opaque bag. It was ensured that allocation was concealed for participants and investigators enrolling participants.

Intervention

Spraino was given to the intervention group with the purpose of mitigating the risk of lateral ankle sprain, while the control group was a do-as-usual comparator. Spraino comprises a set of adhesive patches, which are attached along the lateral edge of the shoe (figure 1). The front patch covers 2–4 mm of the shoe sole while the rear patch does not cover the edge (online supplementary video). Spraino is intended for use in indoor sports and has a reported durability of 20–40 hours of activity.¹⁸

The intervention group received Spraino and application instructions on the same day of inclusion, along with a leaflet (online supplementary appendix S5) containing information on how to order new patches and how to report adverse events associated with its use. They were encouraged to use Spraino during all indoor sport activities. Participants of both groups were also permitted to use (or keep using) any other injury preventive measure of their choice.

Patient and public involvement

Questionnaires and SMS questions were piloted and redesigned with help from 25 athletes. Twenty intervention group participants gave post-trial feedback on both the intervention and study design and conduct. The National Olympic Committee created awareness and helped recruit participating teams.

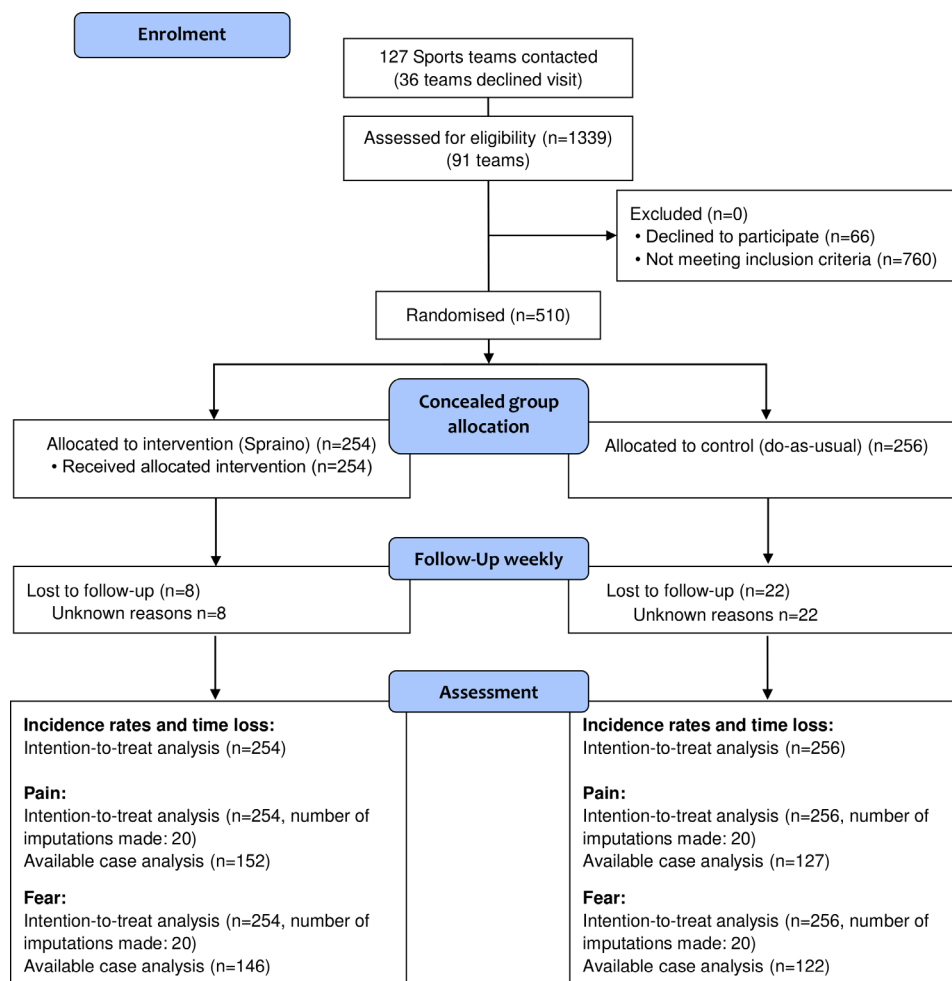


Figure 3 Consolidated Standards of Reporting Trials flow diagram.

Injury registration and data collection

The participants completed a baseline questionnaire¹⁹ (online supplementary table S2), from which mobile phone numbers were obtained to prospectively collect data in SMS-Track^{20 21} through

answers to 6 weekly standardised questions (online supplementary figure S3).

When replying to the SMS questions, participants were required to report: (Q1,Q2) their weekly training and match exposure; (Q3) whether they had incurred a lateral ankle sprain; (Q4) whether their participation was restricted due to a lateral ankle sprain; (Q5) whether they used any ankle injury prevention measure; (Q6) whether they adhered to the intervention. Reminder messages were sent out after 48 hours if an answer to a text message had not been collected. They received a reminder phone call if answers had not been received for two consecutive weeks.

If a lateral ankle sprain, or a participation restriction due to an ankle-related problem, was reported via the SMS system, a follow-up telephone interview was conducted by a member of the research team (online supplementary figure S3). If a lateral ankle sprain was incurred, a detailed injury registration form was completed (online supplementary table S4).

The occurrence of adverse events related to the use of Spraino was closely monitored by a member of the research team.

Outcome measures

Being exploratory, our trial was designed without a predetermined hierarchy among outcome measures. Data on contact and non-contact lateral ankle sprains, as well as in-trial first-time injuries and injury recurrences were documented. A contact sprain was defined as an injury incurred by stepping/landing directly onto an

	Spraino	Control	Total
Participants, n	256	254	510
Male, n (%)	146 (57)	146 (57)	292 (57)
Age, mean (SD)	22.3 (4.0)	23.0 (4.5)	22.7 (4.3)
Height (cm), mean (SD)	181 (10)	182 (11)	182 (11)
Body mass (kg), mean (SD)	80.8 (14)	80.3 (14)	80.5 (14)
Fear*, median (IQR)	70 (40–90)	70 (50–90)	70 (40–90)
Pain†, median (IQR)	2 (0–3)	1 (0–2)	1 (0–3)
Sport, n (%)			
Handball	204 (80)	205 (81)	409 (80)
Basketball	26 (10)	31 (12)	57 (11)
Badminton	26 (10)	18 (7)	44 (9)
Weekly practice (hours), mean (SD)	6.1 (3.1)	6.1 (3.0)	6.1 (3.0)
Level of play, n (%)			
League	10 (4)	12 (5)	22 (4)
First division	80 (31)	78 (31)	158 (31)
Second division	64 (25)	70 (28)	134 (26)
Third division	102 (40)	94 (37)	196 (38)

*Fear of ankle sprain during primary sport (100=no fear, 0=highest fear imaginable).

†Pain in ankle joint during primary sport (0=no pain, 10=highest pain imaginable).

Table 2 Incidence rates, event-related time loss and effectiveness estimates (Sprain vs control)

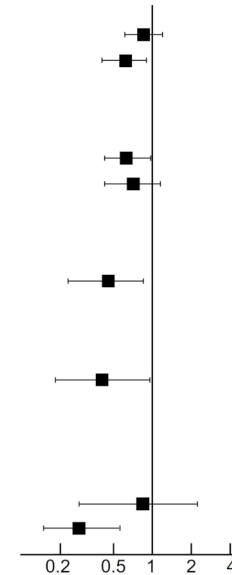
	Spraino (n=256)	Control (n=254)	Spraino versus Control	
			Difference	Ratio*
Total exposure (hours)	18 803	14 185		
Events (151)				
Number	81	70		
Incidence rate†	4.30 (3.30 to 5.30)	4.93 (3.68 to 6.18)	−0.62 (−2.24 to 0.99)	0.87 (0.62 to 1.23)
Time loss (weeks)	1.8 (1.3 to 2.3)	2.8 (2.2 to 3.4)	−1.0 (−1.8 to −0.2)	0.63 (0.44 to 0.92)
Non-contact events (96)				
Number	44	52		
Incidence rate†	2.33 (1.67 to 3.00)	3.67 (2.54 to 4.77)	−1.38 (−2.74 to −0.02)	0.64 (0.42 to 0.98)
Time loss (weeks)	1.9 (1.1 to 2.7)	2.7 (2.0 to 3.4)	−0.9 (−2.0 to 0.2)	0.67 (0.41 to 1.10)
Severe events (50)				
Number	19	31		
Incidence rate†	1.01 (0.51 to 1.50)	2.20 (1.36 to 3.04)	−1.17 (−2.13 to −0.20)	0.47 (0.25 to 0.88)
Non-contact severe events (34)				
Number	12	22		
Incidence rate†	0.63 (0.25 to 1.02)	1.56 (0.82 to 2.30)	−0.89 (−1.74 to −0.04)	0.43 (0.19 to 0.97)
In-trial recurrent events (19)				
Total exposure (hours)	1889	1428		
Number	10	9		
Incidence rate†	5.27 (1.68 to 8.85)	6.29 (1.81 to 10.8)	−0.99 (−6.81 to 4.84)	0.85 (0.32 to 2.24)
Time loss (weeks)	1.1 (0.5 to 1.7)	3.5 (2.1 to 4.86)	−2.3 (−3.7 to −0.9)	0.33 (0.15 to 0.72)

Numbers in parenthesis represent 95% CIs.

Spraino versus control, ratio <1 indicates preventive effect.

*Incidence rate ratio or relative time-loss duration.

†Per 1000 hours of participation in primary sport.



object (ie, opponent's foot). A non-contact sprain was defined as an injury incurred without stepping onto something (other than the floor), regardless of any player-to-player interaction prior to the event. A recurrent sprain was defined as a subsequent sprain to the same ankle previously injured within the trial period.^{22 23}

Time-loss following a sprain was defined as number of calendar weeks with time lost from unrestricted participation due to injury-associated symptoms,²⁴ and was based on the response to Q4 (online supplementary figure S3). As such, an ankle sprain resulted in time-loss if: (Q4=1) the participant had reduced their

participation in their primary sport; or (Q4=2) the participant was affected but still participated. A sprain was considered 'severe' if the participant experienced time-loss for more than 3 weeks.²⁵ Time-loss recordings for each injury was stopped on the first day of a consecutive 3 week period during which the participant could participate unrestricted in his/her primary sport to assure a causal link between injury and acute time-loss.

Additional outcomes included pain in the ankle joint during sport (NRS: 0–10)²⁶ and fear of injury (NRS: 0–100)²⁷ assessed at baseline and follow-up using numeric rating scales (NRS). The

Table 3 Fear of new ankle sprain* and pain in the ankle† at baseline and follow-up, and between-group difference for change adjusted for baseline values (Spraino vs control)

	Mean (95% CI)		Between-group difference for change
	Spraino	Control	
Fear*, intention to treat (n)	254	256	
Baseline	62.9 (59.1 to 66.6)	66.6 (63.1 to 70.1)	
Follow-up	84.7 (82.2 to 87.2)	70.9 (67.2 to 74.7)	13.7 (9.2 to 18.3)
Fear*, available case (n)	146	122	
Baseline	62.9 (59.1 to 66.6)	66.6 (63.1 to 70.1)	
Follow-up	85.0 (82.4 to 87.5)	69.5 (65.2 to 73.9)	15.4 (10.2 to 20.7)
Pain†, intention to treat (n)	254	256	
Baseline	1.9 (1.7 to 2.1)	1.6 (1.4 to 1.8)	
Follow-up	0.6 (0.5 to 0.7)	1.8 (1.6 to 2.0)	−1.2 (−1.5 to −0.9)
Pain†, available case (n)	152	127	
Baseline	1.9 (1.7 to 2.1)	1.6 (1.4 to 1.8)	
Follow-up	0.6 (0.4 to 0.7)	1.9 (1.6 to 2.2)	−1.3 (−1.6 to −1.0)

Numbers in parenthesis represent 95% CIs.

*Fear of sustaining a new ankle sprain during sport was measured on a scale from 100 representing no fear to 0 representing maximum fear. A change of >0 reflects less fear at follow-up as compared with baseline.

†Pain in the ankle during sport was measured on a scale from 0 representing no pain to 10 representing worst pain imaginable. A change of <0 reflects less pain at follow-up as compared with baseline.

intervention group were instructed to report adverse events they associated with Spraino.

Statistical analysis

Lateral ankle sprain incidence rates per 1000 hours of exposure, differences and incidence rate ratios (IRRs, Spraino vs control) were estimated using Poisson regression with the sum of match play and practice hours as exposure. The effectiveness estimates were adjusted for sex, age, type of sport and level of play. Injury recurrence was estimated similarly but only containing exposure from in-trial injured participants. Mean time loss for participants who sustained an ankle sprain was calculated using negative binomial regression. Robust standard errors were calculated to adjust for the repeated nature of measurements (within-participant correlation).

Change in fear of sustaining an ankle sprain, and change in ankle pain, from baseline to follow-up, were calculated using negative binomial regression, adjusting for the values reported at baseline.²⁸ Multiple imputations by chained equations were performed to account for missing values.²⁹ The imputation procedure included variables (age, sex, group allocation and type of sport) prehypothetised to potentially predict missing information. Data were analysed using the *mi estimate* command in Stata (20 imputations) which first runs the estimation command on each imputation separately and then combines results using *Rubin's rule*.³⁰ Analyses were also conducted for participants with full information only (available case analysis).

Statistical analyses were conducted in Stata/IS V.13.1 and performed as intention to treat using inverse probability-of-censoring weighting to account for participant dropout.^{28 31} Adhering to the intention-to-treat principle, Spraino adherence and cointerventions were not taken into account in the analysis. The outcome assessor was blinded to group allocation.

Deviations from registration

Five outcomes were not prespecified in the ClinicalTrials.gov registration. First-time and in-trial recurrent events were combined to investigate (1) the overall effectiveness on injury severity (time-loss), (2, 3) injury mechanism (non-contact sprains and associated time loss), (4) rate of severe ankle sprains and (5) time loss for in-trial recurrences. These measures were missed in oversight during the registration process but added to the analysis plan (4 December 2018) before the trial was analysed and unblinded (26 December 2018). The full trial protocol is available as online supplementary appendix S6 and results of all prespecified outcomes are found in online supplementary table S1.

Table 4 Intervention-related adverse events leading to harm

Participant info	Event report to hotline
Handball player, female 19 years	'I rolled over due to the tape. Maybe it was placed wrong.' (Reported as having occurred twice)
Handball player, female 20 years	'Had a slipping incident (due to Spraino) at training where I fell and got some bruises. Nothing serious though.'
Handball player, male 22 years	'I had an existing groin injury that I felt got worsened through an outwards rotation due to the tape.'
Badminton player, male 23 years	'Rolled over twice and (I am) 100% certain it is due to the tape. Jumping towards my right when my foot slides underneath me.' (Reported as having occurred twice)
Handball player, male 29 years	'I felt that it was the tape that made me twist my ankle. Took it off afterwards.'
Badminton player, male 20 years	'Made a lunge with my left leg and twisted my ankle. Felt like the tape increased the twist.'

RESULTS

Recruitment and trial completion

Five hundred and ten participants were recruited and randomised from 1339 approached athletes of which 576 were eligible for inclusion (figure 3). Four hundred and eighty participants completed the trial: 246 in the intervention (Spraino) group and 234 in the control (do-as-usual) group. Completion was defined as having responded at least once to the weekly text messages. Our prospective registration of injuries was originally specified to be conducted over a 52-week period. However, as the number of events required for statistical analyses was achieved sooner than anticipated, the trial was halted on 5 October 2018 (9 months average follow-up). The mean number of participating weeks was slightly higher in the intervention group compared with the control group (20.7 vs 18.2 weeks).

Trial population

The mean age of participants was 22.7 years, 57% were men and the majority were handball players. No clinically relevant between-group differences appeared present (table 1) and no baseline hypothesis testing was undertaken, as suggested by the CONSORT group.^{14 32}

Intervention effectiveness on incidence rates and incidence-related time loss

A total of 151 lateral ankle sprains were sustained during the trial, of which 96 were categorised as non-contact injuries. Fifty injuries were categorised as severe. The injury incidence rate (sprains per 1000 hours of exposure) was lower in the intervention (Spraino) group compared with the control (do-as-usual) group for all collected outcomes (table 2; online supplementary table S1).

The IRR was 0.87 (95% CI 0.62 to 1.23) for any type of lateral ankle sprain, with a mean time loss of 1.8 weeks (95% CI 1.3 to 2.3) in the intervention (Spraino) group and 2.8 weeks (95% CI 2.2 to 3.4) in the control (do-as-usual) group, resulting in a time-loss difference of 1 week (95% CI -1.8 to -0.2; table 2). The 96 non-contact sprains occurred at a lower rate in the intervention group compared with the control group (IRR of 0.64; 95% CI 0.42 to 0.98) with a time-loss difference per non-contact sprain of 0.9 weeks (95% CI -2.0 to 0.2). For all severe lateral ankle sprains, the IRR was 0.47 (95% CI 0.25 to 0.88) and for severe non-contact sprains the IRR was 0.43 (95% CI 0.19 to 0.97), both favouring the intervention group.

The 19 in-trial injury recurrences occurred at similar rate in the two groups (IRR of 0.85; 95% CI 0.31 to 2.34), with 2.3 weeks (95% CI -3.7 to -0.9) less event-related time loss in the intervention (Spraino) group (table 2).

Intervention effectiveness on fear and pain during sport

Four hundred and fifty-five participants provided full information on fear and pain at baseline, while 281 provided full information at follow-up. The mean fear of sustaining an ankle sprain during sport decreased in both groups. A between-group difference of 13.7 points (95% CI 9.2 to 18.3) was observed (table 3). The mean level of pain in the ankle decreased in the intervention group while it increased in the control group. A between-group difference of -1.2 points (95% CI -1.5 to -0.9) was observed (table 3).

Adherence

Full adherence in the intervention group was defined as having reported to use Spraino for at least 75% of the week, during all weeks of participation. This was observed in 31 (13%)

participants, while 49 (20%) reported not to have used Spraino at all. The 80% of the intervention group participants, who reported to have used Spraino, were adherent for 68% of the participating weeks. Treatment contamination was observed whereby 5 (3%) participants in the control group reported use of Spraino.

Harms

Six participants reported eight adverse events leading to minor harms during the trial (table 4). Of these, four participants experienced harm in the form of an ankle sprain.

DISCUSSION

This trial was designed to assess proof-of-principle of Spraino by determining preliminary effectiveness and safety in lateral ankle sprain injury prevention, when added to do-as-usual injury prevention among subelite indoor sport athletes with a previous sprain injury. In general, we found that Spraino had a protective effect across outcome measures, as the incidence rate of non-contact sprains and severe sprains was lower for those randomised to Spraino than those randomised to usual care.

Interpretation

Most of the injuries incurred in this trial occurred via a non-contact injury mechanism. This aligns with previously published literature^{28 33} and was the case for 74% (52 out of 70) of sprains in the control (do-as-usual) group and 54% (44 out of 81) in the intervention (Spraino) group. The lower incidence rate and proportion of non-contact sprains in the intervention group brings notion to the thought of excessive friction as an important risk factor for lower extremity injuries in sports.^{4-7 34}

Average time loss was significantly 37% lower in the intervention (Spraino) group. They returned to sports participation without restriction 1 week faster following injury on average, than did controls. For in-trial recurrent events, event-related time loss was 67% lower in the intervention (Spraino) group (1.1 vs 3.5 weeks).

The additive effectiveness of Spraino on injury incidence rate found in this study is comparable to the effects of other preventive measures (ie, exercise and external prophylactic measures like bracing and taping) when these are compared with no measure.¹⁵ That Spraino was associated with lower injury severity contrasts directly with the results of previous studies, that investigated other prophylactic measures, who found no reduction in time-loss per injury.³⁵ Our results support the premise that Spraino can mitigate the risk of sprain injuries among indoor sport athletes, and that its use is not associated with severe adverse consequences.

The intervention (Spraino) group had 21.8 points lower fear of ankle sprain injuries; the between-group difference of 13.7 points is less than minimal clinically important difference (MCID = 19.0)³⁶ but could still be of some importance with persisting fear of injury being regarded as a major hindrance to sports activity.²⁷ Pain is a frequent and debilitating problem following musculoskeletal injury. The between-group difference of 1.2 points (11 NRS) in ankle pain, favouring Spraino, may not be clinically relevant considering an MCID of 2 points.²⁶ However, our findings related to fear and pain suggest that Spraino may have further beneficial effects, aside from injury prevention.

Implications

Considering the high risk of both initial and recurrent ankle sprains in indoor sports,^{1 33} and with 40% of the approached

population being eligible due to having sustained an ankle sprain within 24 months prior to the trial, prevention seems relevant to a large population of indoor sport athletes. Clinicians should consider advising indoor sport athletes to use Spraino given its effectiveness in lowering the incidence rate of lateral ankle sprains, without any severe adverse consequences. Spraino may be particularly relevant for those athletes with subjective reporting of pain, fear of injury and ankle instability.³⁷

Strengths and limitations

We acknowledge several limitations. First, not all presented outcomes were preregistered. These outcomes were however added before analysis and fit the overall pattern of Spraino effectiveness. Second, only passive surveillance of harms was used, which generally yields fewer adverse events than active monitoring.³⁸ Third, participants were not blinded to the intervention. This is not regarded as a limitation to the objective outcomes: incidence rate and time loss. However, the risk of bias is high on the subjective outcomes (fear and pain).

We did not control for the use of other injury prevention strategies, since Spraino was introduced as an additional preventive measure. However, the combination of less than perfect adherence to Spraino, treatment contamination and do-as-usual injury prevention in the control group makes the effectiveness across all outcomes highly promising. The intervention mirrors real life use of Spraino as all athletes were responsible for applying and replacing the product.

What are the findings?

- Spraino shows promising effects and appears safe when used to mitigate the risk of non-contact lateral ankle sprain injuries in indoor sport athletes.
- Athletes randomised to Spraino had a 53% lower incidence rate of severe lateral ankle sprain injuries than did the control athletes.
- Spraino seems to reduce ankle-related pain and fear of lateral ankle sprain injuries.

How might it impact on clinical practice in the future?

- Clinicians might consider recommending that indoor sports athletes with a previous lateral ankle sprain injury use Spraino.
- Spraino may be a relevant add-on for athletes in instances where previous preventive measures have been ineffective.

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Contributors TBG, FGL and UK conceived the study. KT, TB, ED, PBP and MBC designed the trial. TBG and UK were grant holders. SM managed the collection of data under the supervision of MBC. JST provided statistical and epidemiological expertise and conducted the statistical analyses. TB, KT and ED provided clinical scientific expertise throughout the study. KT supervised the study in its entirety. All authors contributed to refinement of the article and approved the final manuscript.

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Competing interests TBG is the founder of Spraino ApS. FGL is a paid employee in Spraino ApS. Spraino ApS was responsible for provision of Spraino. The conflict was accommodated by restricting Spraino ApS and authors FGL and TBG from having any deciding role in the design of the study, in the execution, analyses, interpretation of data, or decision to submit results. Statistical analyses were performed externally by JS who was blinded to group allocation. KT had full authority of the trial administration. The three senior clinical researchers (KT, TB and ED) had full authority in terms of submission for publication. Copenhagen Center for Health Technology (CACHET) and Innovation Fund Denmark had no scientific role in the trial. KT is an Associate Editor of the *British Journal of Sports Medicine*. ED is a Senior Associate Editor of the *British Journal of Sports Medicine* in the area of foot and ankle injuries.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Ethics approval Ethics approval was obtained from The North Denmark Region Committee on Health Research Ethics on 5 July 2017.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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