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Brace beats Balance Board

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SUMMARY

Physical activity is crucial for a healthy lifestyle, and sport is an important source of physical activity for most of us. Sport is also good for a healthy mind and spirit. Furthermore, participation in sport helps development in accountability, dedication, and leadership, and has many other less known benefits, like improving rehabilitation and quality of life in the chronically ill. Putting it all together, being physically active participating in a sport is a winning combination.

In the Netherlands 65% of the population is active in sport on a regular basis. The aim of our National Olympic Committee is to boost public sport participation to a level of 75% in the coming years. This includes for instance, your mother running up and down the tennis court, but also top athletes who competed in Rio 2016. In fact this year the Netherlands had one of the largest Dutch Olympic delegations ever, in itself an acknowledgement of the importance of sport for our modern society.

Like any good medicine, sport has its side effects, mainly in the form of injuries. Ankle sprains are the most common recreational sports injury, making up about 20% of all adult sports injuries. In over 30% of these ankle sprains it concerns a recurrence. All these sprains are not only a burden for the athletes but also for society. The annual total medical cost of ankle sprain is estimated at €45 million annually, and the estimated cost of absenteeism at €55 million, this leads to a total estimated cost of €100 million annually. Obviously, the high incidence, recurrence and cost of ankle sprain in sport warrants the use of preventive measures. Back in 2006 the Royal Dutch Physiotherapy Association was the first to implement advice on the prevention of ankle sprain in their guideline for treatment of acute ankle sprain. The main measures mentioned by this guideline were neuromuscular (NM) exercises and bracing or a combination of the two, while at the time their cost-effectivity was unknown. The main study in this thesis deals with the abovementioned issues by directly comparing bracing versus NM training and a combination of both evaluating the cost-effectiveness of these measures.

Chapter 2

The objective of the Cochrane review described in Chapter 2 was to assess the effects (benefits and harms) of interventions for preventing ankle ligament injuries and re-injuries. Randomised and quasi-randomised controlled trials evaluating interventions for preventing ankle ligament injuries were eligible for inclusion. Two review authors independently performed study selection, risk of bias assessment and data extraction. A total of 47 trials, including 29,752 participants, were included. Although the interventions were heterogeneous, and outcomes varied, the data from 33 trials could be pooled for the primary outcome 'incidence of ankle ligament injury'. Overall the risk of bias in the pooled studies was low to moderate. Most participants were high school athletes, recreational athletes (age mainly 18 to 35 years) or military recruits. The interventions tested in the included trials fell into seven main preventive strategies: footwear, taping, bracing, NM training, multifaceted exercise programs, insoles and stretching. The following results concern pooled data for incidence of 'total ankle sprains'. Two trials (1463 participants) showed that there is limited inconclusive evidence regarding the effectiveness of high-top shoes versus low-top shoes (OR 1.02, 95% CI 0.52 to 2.03). The only trial concerning taping versus controls (2,562 basketball player games) showed a significant reduction in the occurrence of ankle sprains (OR

0.44, 95% CI 0.24, 0.79). Nine trials (7886 participants) that compared the use of different brace types to controls showed a significant reduction in the occurrence of ankle sprains (OR 0.38, 95% CI 0.31 to 0.47). Nine trials (3845 participants) that compared NM training to controls showed a significant reduction in the occurrence of ankle sprains (OR 0.59, 95% CI 0.47 to 0.72). Six trials (6,412 participants) that compared multifaceted exercise programs to controls showed a significant reduction in the occurrence of ankle sprains (OR 0.55, 95% CI 0.43 to 0.71). Three trials that compared stretching to controls showed no effect in the occurrence of ankle sprains (OR 0.71 95% 0.44 to 1.13). Two trials (676 participants) investigated insoles versus controls which showed no effect in the occurrence of ankle sprains (OR 0.73, 95% CI 0.37 to 1.44). Finally, two trials (411 participants) that compared different brace types to NM training showed a significant reduction in the occurrence of ankle sprains in favour of bracing (OR 0.55, 95% CI 0.43 to 0.71). In this review overall taping, bracing, NM training and multifaceted exercise programs were found to prevent ankle ligament injuries, although quality of studies was diverse. For prevention of first time ankle ligament injuries, evidence was only found for bracing. For prevention of recurrent ankle ligament injury, taping, bracing, NM training and multifaceted exercise programs all showed benefits. Finally, high-top shoes, stretching and insoles were not shown to prevent ankle injuries.

Chapter 3

This chapter describes the design of a randomised controlled trial (RCT) that evaluated the effect of the combined use of bracing and NM training against the individual use of either bracing or NM training alone on ankle sprain recurrences after usual care. Athletes who had recently sprained their ankle were included in this study. After participants had finished ankle sprain treatment by means of usual care, they were randomised to any of the three study groups. Group 1 received an eight week NM training program that was previously proven effective, Group 2 received a sports brace to be worn during all sports activities for the duration of one year, and Group 3 received a combination of the NM training program and a sports brace to be worn during all sports activities for the duration of eight weeks. The primary outcome measure was incidence of ankle sprain recurrences. Secondary outcome measures included the direct and indirect costs of recurrent injury and compliance with the interventions. These data were collected by a monthly injury questionnaire during a follow-up of one year. By this questionnaire compliance to the interventions was also measured. In case of a recurrent ankle sprain a cost-diary was completed by the participant. The RCT described in this chapter was the first to directly compare these secondary preventive measures.

Chapter 4

This chapter presents the results of the RCT described in chapter 3. The objective of this study was to evaluate the effectiveness of combined bracing and NM training, or bracing alone, against the use of NM training on recurrences of ankle sprain after usual care. For this purpose 384 athletes, who had sustained a lateral ankle sprain, were included and randomised to one of the three interventions. During one year, 69 participants (20%) reported a recurrent ankle sprain: 29 (27%) in the NM training group, 17 (15%) in the Brace group and 23 (19%) in the Combi group. The relative risk for a recurrent ankle sprain in the Brace group versus the NM training group was 0.53 (95%CI 0.29 to 0.97). No significant differences were found for time losses or costs due to ankle sprains between the intervention groups. Bracing was concluded to be superior to NM training

in reducing the incidence but not the severity of self-reported recurrent ankle sprains after usual care. Although current clinical guidelines are vague on the prescription of NM training and bracing, these study results support the prescription of bracing as single secondary preventive measure for the prevention of self-reported recurrences. Furthermore, as in this study bracing was proven effective when prescribed during sports for one year, the prescription period of brace use in athletes was advised to be extended, instead of phased out.

Chapter 5

In addition to the evaluation of the preventive effectiveness of separate and combined bracing and NM training in the previous chapter, the current chapter evaluates the costs associated with the interventions. This question of efficiency was answered through a cost-effectiveness analysis, valuing incremental costs of both interventions to - in the case of injury prevention - the incremental reduction in injury risk. The necessary cost data were registered alongside the injury data in the trial described in chapter 4. In case of an ankle sprain a cost-diary was completed by the participant. Costs related to the recurrent ankle sprains were measures from a societal perspective, i.e. including costs for society, like absence from work. Complete cost diaries were retrieved from 67 of the 69 injured participants (97%). The incremental cost-effectiveness ratio (ICER) was calculated with the Combi group as reference. As such, ICER presents the incremental costs of either the NM training or Brace group to prevent one ankle sprain recurrence in comparison with the Combi group. The ICER of the Brace group in comparison with the Combi group was €-2828.30, based on a difference in mean cost of €-76.16 and a difference in mean effects of 2.68%. The ICER of the NM training group in comparison with the Combi group was €310.08, based on a difference in mean cost of €-28.37 and a difference in mean effects of 9.15%. Cost-effectiveness planes showed that bracing was found to be the dominant intervention over both NM training and the combination of both measures, providing a more effective and less expensive secondary preventive measure. A limitation of this study was that it only evaluated the incremental costs and effects of braces or NM training as separate measures against their combined use; in other words a control group was missing. Consequently, no conclusions could be drawn on the effectiveness and cost-efficiency of each of the separately implemented measures. It was also noted that clinical care is provided to a single patient, while the presented results concerned an outcome over a group of patients. As such, it was stressed that findings from this study do not necessarily reflect the best preventative option for each individual athlete.

Chapter 6

Previous research has shown that athletes with higher perceptions of susceptibility to re-injury are more likely to comply with their rehabilitation program. Accordingly, to optimise preventive effects for the individual, the aim of the study in this chapter was to describe the association between potential predictor variables and compliance with the interventions described in the RCT in chapter 4. A secondary analysis of compliance data from this RCT was performed to obtain a descriptive statistical model linking participants' person-related potential predictor variables with the monthly compliance with the three interventions. From the obtained model it was concluded that having had a previous ankle injury was significantly associated with a higher compliance with all of the preventive measures trialed. Overall, compliance with bracing and the combined intervention was significantly lower than the compliance with NM training. Per group

analysis found that participating in a high-risk sport, like soccer, basketball and volleyball, was significantly associated with a higher compliance with bracing or a combined bracing and NM training. In contrast, participating in a high-risk sport was significantly associated with a lower per group compliance with NM training. Practitioners are advised to take into account these variables when prescribing preventive NM training and/or bracing.

Chapter 7

Despite the substantial evidence from chapters 2, 4 and 5 that bracing is an effective measure against ankle sprains, surveys in high risk sports, like recreational soccer and basketball, found that only 27% and 33% of athletes wore an ankle brace, respectively. This raises questions in regards to the implementation and barriers of brace use. In regards to braces, next to a lack of public knowledge on effectiveness, the perceived comfort of braces is argued to be an important barrier against brace use. Subjective factors like comfort need to be addressed when promoting the use of ankle braces. Therefore, the aim of the study described in chapter 7 was to systematically evaluate the perceived ease of use, quality, comfort, stability, hindrance and overall satisfaction of three different contemporary brace types in three types of sports. Secondary outcome measure was participants' willingness to buy the tested brace. In this randomised comparative user survey 29 soccer players, 27 volleyball players and 31 runners were included. Three different brace-types, a compression brace (C), a lace-up brace (L) and a semi-rigid brace (S), were worn during sports participation for three consecutive weeks per brace. Overall, the three brace types received high mean scores for ease of use and quality. Soccer players preferred the compression brace over both alternatives, considering the significantly higher scores for comfort (C 4.0 vs. S 2.8, L 3.5), hindrance (C 3.7 vs. S 2.8, 2.9), overall satisfaction (C 3.6 vs. S 2.5, L 3.0) and highest willingness to buy this brace. Volleyball players preferred the lace-up brace over both alternatives, considering the significantly higher scores for stability (L 4.2 vs. S 3.3, C 3.2), overall satisfaction (L 3.8 vs. S 3.0, C 3.0) and highest willingness to buy this brace. Runners preferred the compression brace over both alternatives considering the significantly higher score for hindrance (C 3.6 vs. S 2.9, L 2.8) and highest willingness to buy this brace. The conclusion was that the tested ankle brace-types all scored high on perceived ease of use and quality, though, the brace types significantly differed with respect to subjective evaluation of comfort, stability, hindrance, overall satisfaction and willingness to buy the brace. Soccer players and runners preferred the compression brace, while volleyball players preferred the lace-up brace. The results from the study in this chapter will assist athletes, coaches and practitioners in selecting an optimal ankle brace for ankle sprain prevention.