Brace beats Balance Board

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Interventions preventing ankle sprains; previous injury and high-risk sport participation as predictors of compliance.

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ABSTRACT

Objectives: To describe the association between participants' person-related potential predictor variables and cumulative compliance with interventions for preventing ankle sprains: neuromuscular training, wearing an ankle brace and a combined training and bracing.

Design: Secondary analysis of compliance data from a randomised controlled trial (RCT) comparing measures preventing ankle ligament injuries.

Methods: Ordinal regression with a backward selection method was used to obtain a descriptive statistical model linking participants' person-related potential predictor variables with the monthly cumulative compliance measurements for three interventions preventing ankle ligament injuries.

Results: 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.

Conclusions: Future studies should include at least registration of previous ankle sprains, sport participation (high- or low-risk), experience in NM training and hours of sport exposure as possible predictors of compliance with interventions preventing ankle sprains. Practitioners should take into account these variables when prescribing preventive neuromuscular training or bracing.

INTRODUCTION

Preventive interventions are commonly used in various sports to reduce the number of sports injuries. When translating evidence-based preventive interventions into daily practice in sports, an important issue to address is compliance [1]. In sports injury prevention research, compliance is a term used to indicate the athlete's correct execution of the prescribed intervention [2]. In the preferred research design setting for the evaluation of the efficacy of sports injury preventive interventions, i.e. a randomized controlled trial (RCT), compliance can be optimized by the use of a well-defined protocol that must be complied with. This compliance can be monitored by researchers, practitioners, coaches, or athletic trainers or self-monitored by the participants.
In recent years, there has been a trend towards more effectiveness studies to determine how well efficacious interventions work when applied in a practical context [3]. In a previous ankle sprain prevention trial on home-based neuromuscular (NM) training by our group, only 23% of the participants fully complied with the protocol. A secondary per protocol analyses showed that the established intervention effect was over threefold higher for fully compliant participants when compared to the controls [2]. In line with these results, Steffen et al [4] found a lower risk for lower extremity injuries in high compliant athletes versus medium compliant athletes with the FIFA11+ program in soccer. Furthermore, McGuine [5] et al recently provided evidence for the use of sports braces as preventive measures in male and female high school basketball athletes, both with and without a previous history of an ankle injury. In 59% of the training sessions and games, participants were compliant with the preventive brace advice, as monitored by athletic trainers. As this and an earlier study [2] showed, there can be degrees of usage of an intervention whether it is wearing protective equipment or performing a training programme. What is lacking from the literature is a direct comparative assessment of the possible predictors of compliance with home-based interventions preventing ankle ligament injuries.

In a recent RCT, the cost-effectiveness of secondary ankle sprain prevention by the use of NM training or bracing was assessed against the combined use of both NM training and bracing [6]. Although bracing was found to be superior to NM training for the prevention of recurrent ankle sprains, as could be expected, the compliance with each intervention varied substantially. In the aforementioned studies, higher compliance resulted in a lower relative risk of a recurrent ankle sprain. To predict compliance with sport injury rehabilitation Taylor and May [7] applied the protection motivation theory. They concluded that athletes with higher perceptions of susceptibility to re-injury were more likely to adhere to their rehabilitation program. Accordingly, at least in theory we should be able to optimise preventive effects for the individual if we can tailor intervention advice, taking into account person-related predictor variables associated with higher compliance. Therefore, the aim of this study was to describe the association between person-related potential predictor variables and cumulative compliance with prescribed interventions in this RCT [6].

METHODS

This study is a secondary analysis of data from a previously published RCT on the cost-effectiveness of prevention of ankle sprain recurrences [6, 8, 9]. The main study design and interventions have been described in detail elsewhere [9]. The study design, procedures

and informed consent procedure were approved by the Medical Ethics Committee (number 31785.029.10) of the VU University Medical Centre, the Netherlands. Trial register number NTR 2157.
All participants provided written informed consent. Briefly, an RCT was conducted in athletes (n = 384) who had sprained their ankle. All participants received treatment according to usual care, after which they were randomized to one of three intervention groups. Participants allocated to the NM training-only group received an eight week unsupervised NM training program. Participants in this group received a balance board (Avanco AB, Sweden), exercise sheets, and an instructional DVD of the exercises. Participants allocated to the brace-only group received a semi-rigid ankle brace (Aircast A60, DJO) to be worn during all sports activities for the duration of one year and an instruction sheet on brace use. A third combination group received both the NM training program and a sports brace to be worn during all sports activities for the duration of eight weeks. The instruction sheet on brace use, exercise sheet on NM training and videos of the exercises were also provided on a website that was accessible only to the relevant intervention group.

During a one year follow-up, participants self-reported compliance with the prescribed intervention through items in the monthly questionnaire. The item(s) on compliance are presented in Table 1. The term fully compliant was used for participants who reported 'always (>75%)' on average for the respective items. The term partially compliant was used for participants who reported 'most of the time (about 50%)' on average for the respective items. Participants who reported 'never (0%)' or 'sometimes (about 25%)' on average for the respective items were considered not to have complied with the prescribed program. Although these three categories were chosen arbitrarily, we believe that adding percentages to the description and combining the first two options 'never (0%)' and 'sometimes (25%)' into a single category of 'not compliant' minimizes central tendency bias and differentiates between participants who did and did not comply with the prescribed program.

Table 1. Compliance item(s) and answer options per intervention group.

Group	Compliance item	Answer options
NM training (one item)	Did you perform the exercises as prescribed in the last four weeks?	No, never Yes, sometimes (about 25% of the prescribed training sessions) Yes, most of the time (about 50% of the prescribed training sessions) Yes, always (more than 75% of the prescribed training sessions)
Brace (two items)	Did you wear the brace during training as prescribed in the last four weeks? Did you wear the brace during competition as prescribed in the last four weeks?	No, never Yes, sometimes (about 25% of the training/competition sessions) Yes, most of the time (about 50% of the training/competition sessions) Yes, always (more than 75% of the training/competition sessions)
Combination (three items)	Did you perform the exercises as prescribed in the last four weeks? Did you wear the brace during training as prescribed in the last four weeks? Did you wear the brace during competition as prescribed in the last four weeks?	No, never Yes, sometimes (about 25% of the prescribed/training/competition sessions) Yes, most of the time (about 50% of the prescribed/training/competition sessions) Yes, always (more than 75% of the prescribed/training/competition sessions)

As no valid measurement or consensus on self-reported compliance with training programs or brace use exists, the choice to measure compliance through these items was based on the experience in a previous trial [10]. The monthly compliance item scores were recoded into one overall score. As loss to follow up was only 6% we decided to impute the compliance data via 'last observation carried forward' method. The scores were recoded into a numerical variable (i.e. 0% = 0; 25% = 1; 50% = 2 and >75% = 3). A mean compliance score across participants allocated to each intervention was calculated and used in the analyses.

In the current study, the association between person-related potential predictor variables and compliance was the primary outcome. Consistent with other studies [2], we assumed that a higher compliance with these interventions would generate a larger decrease in injury risk. Person-related potential predictor variables were derived from the available baseline dataset and included: intervention group, age, previous ankle injury, experience with tape/brace use, experience with NM training, high-risk sport participation, education at inclusion, and monthly registered hours of exposure during follow-up. 'Intervention group' was included because full compliance to the intervention groups differed substantially (NM training 45%, brace 23% and combination 28%). Interactions between age and self-motivation for home exercise completion have also been documented [11]. A previous ankle sprain has been showed to be followed by a higher perception of susceptibility to re-injury and therefore a higher compliance with the intervention is likely [12]. If NM training has been performed previously, there will be participant insight into the features of the intervention program, and possibly consumer satisfaction with the intervention which makes a higher compliance likely [13]. For

experience with tape/brace use, the previous argument also supports inclusion of this variable. When incidence of injury is high in a specific sport, this could be followed by a higher perception of susceptibility to injury and therefore a higher compliance is likely for high-risk sport participation [12]. In medication trials, low education level is shown to be a predictor of non-compliance and treatment discontinuation [14]. Low compliance versus high compliance athletes with an injury prevention program in football were linked to a three times lower exposure [15].

Several variables were not included in the candidate statistical models because of insufficient evidence or clinical reasoning relating them to compliance. These included: gender, weight, height, sport experience (years), severity of inclusion sprain (minor / severe) and medical treatment (medical / non-medical). Although it is known from other research areas that in general females are more compliant with instructions than males, we are not aware of studies that have shown specifically that females are more compliant to preventive NM training and bracing than men. Furthermore, we had to restrict the number of included person-related potential predictor variables due to the limited number of participants per group and thus power.

Ordinal regression with a backward selection method was used to obtain a descriptive model of the association between participants' person-related potential predictor variables (Table 3) and the monthly compliance measurements to the three interventions. In the construction of the ordinal regression model, a backward elimination procedure with a $p > 0.10$ criterion for variable elimination was applied. The interventions for the NM training group and combination group lasted only two months compared to twelve months for the brace group. Therefore, as a sensitivity analysis, we repeated the procedures of the model with the same variables to evaluate compliance for the brace group in the first two months only. The assumption that the relationships between independent variables and different adherence groups are the same for the three adherence groups was tested using a test of parallel lines ($p>0.05$). We modeled the association between person-related potential predictor variables and the 'cumulative compliance', as in our model the outcome compliance was categorized into: no compliance (participants who executed 25% or less of the prescribed intervention), partial compliance (participants who executed about 50% of the intervention) and full compliance (participants who executed 75% or more of the prescribed intervention). For readability, we hereafter use the term 'association with compliance', while technically we mean 'association with cumulative compliance'.

RESULTS

Forty-four participants had neither received nor started their allocated intervention and were excluded. Data from 340 participants were included in the analyses. The intervention groups were comparable on all measured variables at baseline. A complete overview of baseline variables has been published elsewhere [6]. The drop-out rate during the trial was also similar between groups. Forty-nine (45%) of the NM training group athletes, 27 (23%) of the sports brace group athletes, and 34 (28%) of the combination group athletes indicated that they had fully complied with their allocated intervention. The compliance percentages, number of injuries, hours of exposure and incidence rates for all groups are presented in Table 2.

Table 2. Participants, recurrent ankle sprains, exposure and incidence rate for the three different intervention groups per compliance category.

Compliance sub-group	Participants n	%	Recurrent ankle sprains n	Exposure to sports participation total h	Incidence rate = recurrent ankle sprains / 1000h (95%CI)
NM Training					
Total	110	100	29	11,565	2.51 (1.59-3.42)
Full compliance	49	45	16	5,907	2.71 (1.38-4.04)
Partial compliance	31	28	8	3,276	2.44 (0.74-4.13)
No compliance	30	27	5	2,382	2.10 (0.26-3.94)
Sports Brace					
Total	117	100	17	12,678	1.34 (0.70-1.98)
Full compliance	27	23	4	3,309	1.21 (0.02-2.39)
Partial compliance	22	19	4	2,018	1.98 (0.04-3.92)
No compliance	68	58	9	7,351	1.22 (0.42-2.02)
Combination					
Total	122	100	23	12,931	1.78 (1.05-2.51)
Full compliance	34	28	3	3,824	0.78 (0.00-1.67)
Partial compliance	44	36	9	4,802	1.87 (0.65-3.10)
No compliance	44	36	11	4,305	2.56 (1.05-4.07)

Overall, a significant positive association between compliance and the interventions was found for participants with a history of 'previous ankle sprain'. In other words, having had a previous ankle injury increased the likelihood of a higher compliance with any of the interventions (OR 1.72; 95% CI 1.09-2.70). Compliance in the brace and combination group was significantly lower compared to compliance in the NM training group (brace vs. NM training OR 0.28 (95% CI 0.17-0.47) and combination vs. NM training OR 0.58 (95% CI 0.36-0.95)). Furthermore, participants playing a high-risk sport had an increased probability of being more compliant with any of the interventions (OR 1.53; 95% CI 1.02-2.29).

Table 3 summarizes the results of the ordinal regression analyses of variables associated with compliance within the three intervention groups. Within the NM training group a significant positive association with compliance was found for participants with a previous ankle injury and experience in NM training. A significant negative association with compliance was found for those who played a high-risk sport at inclusion. Furthermore, a higher number of hours of sports per month is associated with a higher compliance. Within the brace and combination groups a significant positive association with compliance was found for high-risk sport participants.

Table 3. Association of person-related potential predictor variables with compliance within the 3 intervention groups - results from the ordinal regression analyses.
A: NM Training group, B: Brace group, C: Combination group

A. Significant association of person-related potential predictor variables with compliance for NM Training group

	Variable coding	OR	95% CI	Interpretation
Previous ankle Injury	no prior injury* prior injury	2,23	(1,07-5,29)	Having had a previous ankle injury is associated with a **higher** compliance.
Previous experience NMT	no prior experience* prior experience	2,23	(1,01-4,84)	Having had previous experience with NMT is associated with a **higher** compliance.
Exposition / month	hours/ month	1,07	(1,00-1,14)	Increased hours of sports participation is associated with a **higher** compliance
High- / low-risk sport	low risk sport (e.g., running, tennis, …)* high risk sport (e.g. soccer, basketball, volleyball, …)	0,43	(0,19-0,96)	Participating in a high-risk sport is associated with a **lower** compliance.

B. Association of person-related potential predictor variables with compliance for brace group

	Variable coding	OR	95% CI	Interpretation
High- / low-risk sport	low risk sport (e.g., running, tennis, …)* high risk sport (e.g. soccer, basketball, volleyball, …)	3,39	(1,49-7,44)	Participating in a high-risk sport is associated with a **higher** compliance.

C. Association of person-related potential predictor variables with compliance for combination group

	Variable coding	OR	95% CI	Interpretation
High- / low-risk sport	low risk sport (e.g., running, tennis, …)* high risk sport (e.g. soccer, basketball, volleyball, …)	2,49	(1,27-4,92)	Participating in a high-risk sport is associated with a **higher** compliance.

*reference group

At 2 months follow-up, 48% of the participants in the brace group fully complied with the intervention versus 45% in the NM training group. We performed a sensitivity analysis by analyzing compliance in athletes participating in a high-risk sport for each intervention group after 2 months of follow-up. This analysis showed that of the athletes participating in a high-risk sport 58% were fully compliant with bracing versus 38% who were fully compliant with NM training. This indicates that over a 2 month period, participants in a high-risk sport were more likely to comply with bracing than with NM training.

DISCUSSION

The purpose of this study was to describe the association between participants' person-related potential predictor variables and cumulative compliance with NM training, bracing and the combined intervention. Our results show that having had a previous ankle injury was significantly associated with a higher compliance with all of the preventive measures trialed. Compliance with bracing and the combined intervention was significantly lower compared to compliance with NM training. Per group analysis found that participating in a high-risk sport was significantly associated with a higher compliance with bracing or a combined bracing and NM training, while participating in a high-risk sport was significantly associated with a lower compliance with NM training.

Research on compliance with interventions preventing ankle ligament injuries has mainly focused on interventions in the clinical setting, for example physical therapy. Basset et al [16], conducted one of the few trials that studied compliance with a clinic-based versus a home-based intervention to treat ankle sprains in a study population of mainly athletes (n= 52) and reported significant higher levels of compliance with the physical therapy intervention for the home-based intervention group. The home-based intervention group had comparable results in terms of recovery and treatment compliance when compared to the clinic-based intervention group. However, for several reasons the results from this study cannot be compared to our results. Firstly, the home-based intervention included clinical appointments where patients received treatment information on the home-based program. Secondly, different measures of self-reported compliance were used. Thirdly, this study was concerned with treatment, not prevention, of ankle sprains.

A second study, from Hume et al [17] described injuries and the injury prevention behaviours of players requiring treatment during an Australian Netball Championship. Over the three day tournament, 131 female players (mean age of 18.4 years) were injured and sought treatment. Despite implementation of injury prevention programs, 49% of injured players had previously sustained the same injury, with a direct related recurrent injury in 36% of the cases. In addition to this high number of recurrent injuries, it was found that there was a low awareness of effective preventive measures such as NM training. To improve compliance with injury prevention initiatives, Hume et al [17] suggested targeting school students instead of the netball associations. As these results were all obtained from a cross sectional survey and details of the preventive interventions used were unknown, these results cannot be directly compared to our results. Because the suggestion of targeting specific subgroups of athletes to improve compliance is in line with the current focus on person-related potential predictor variables associated with compliance with the prescribed interventions, then subgroups of athletes with a 'history of previous ankle sprain', a 'history of experience with NM training' and 'high or low risk sport participation for sustaining an ankle sprain' are to be targeted.

One of the main theoretical approaches to predict compliance with sport injury rehabilitation is the 'protection motivation theory'[12]. This theory describes two cognitive processes involved in the decision to adopt protective health behaviors, or alternatively, to produce maladaptive responses: i.e. the threat appraisal process and the coping appraisal process. The threat appraisal process involves a perception of the

severity of a potentially harmful situation (e.g., an athlete's perception of how likely it is that injury severity is a threat to their health). The coping appraisal process involves a perception of how likely a particular course of action reduces or prevents the threat (labeled response efficacy; for example how an athlete's response will be effective). Taylor and May [7] used this theory to predict compliance and reported that athletes with higher perceptions of susceptibility to re-injury were more likely to comply with their rehabilitation program.[7]. This is in line with our finding that having had a previous ankle injury significantly increased overall compliance with the preventive measures. In contrast, a recent study found no influence of injury history on adherence to the FIFA 11+ in female soccer, but that study did not assess this in relation to specific injuries [18]. Taylor and May [7] found that stronger self-belief in the ability to complete the prescribed intervention also increased compliance as did greater expectancy in the benefits of rehabilitation. Therefore, it would be advisable for future studies to investigate the tailored prescription of NM training and different brace types based on individual preference of athletes from different sports, to optimize the chance of the athlete successfully completing the prescribed intervention.

A main limitation for interpretation of the results of this study is the potential of recall bias, as self-reported compliance was measured via a monthly questionnaire. We assigned percentages to the description of the compliance categories to reduce the risk of misclassification. Furthermore, by using separate items for compliance scores on brace use in training and competition we tried to lower misclassification of compliance categories in bracing. Although our method of compliance measurement has been used before [2], there is no consensus on how to measure compliance, and so the internal validity of our study could have been hampered. Even when these limitations are taken into account, our results are of value because the straightforward preventive interventions were applied to a broad population of athletes across a wide age spectrum. Therefore, external validity with respect to athletic populations is high. A major strength of this study is that it was based on the first RCT to directly compare the three interventions: i.e. bracing, NM training and the combined intervention versus each other [6].

Conclusion

In this study, we focused on describing the association of person-related potential predictor variables with compliance with different interventions used to prevent ankle sprains. Our results can give direction to future research conducted to decide which baseline characteristics are of interest as possible predictors of compliance. Future studies should include at least registration of previous injuries (e.g. previous ankle sprains), sport participation (high- or low-risk), experience in NM training and hours of sport exposure as possible predictors of compliance with interventions preventing ankle sprains.

Practical Implications

- The first two months compliance to home-based NM training and bracing during sports is comparable, while combining the two interventions decreases compliance substantially.
- Practitioners prescribing preventive NM training or bracing to athletes should take into account 'history of previous ankle sprains', 'history of experience with

NM training' and 'high or low risk sport participation for sustaining an ankle sprain', to optimize compliance with these interventions.

- Athletes without a history of previous ankle sprains and athletes who did not previously perform home-based NM training are substantially less likely to comply with NM training.
- In contrast, athletes who participate in a sport that is high-risk for sustaining an ankle sprain, like soccer, basketball and volleyball, are substantially more likely to comply with wearing a brace during sports.

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