Reply to Letter to the Editor

Efficacy and Degree of Bias in Knee Injury Prevention Studies: A Systematic Review of RCTs

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We appreciate the thoughtful comments of Dr. Berger regarding our recent publication [1]. He focused on the following methodologic points: randomization methods, concealment of allocations, and masking (blinding). Overall, we are in agreement with the position that every action should be taken to minimize susceptibility to bias by using the most appropriate methods for conducting randomized controlled trials.

However, we are concerned that theoretical judgments were proposed by Dr. Berger without detailed review of the actual studies being evaluated. Specifically, he argues that “in point of fact, it is unlikely that any of the studies were properly randomized, or enjoyed the benefits of allocation

concealment”. In addition, he stated “it is unlikely that even the one study [2] that claimed masking could have been truly masked”.

We should start by examining the specific methods used in the excellent study by Brushoj et al. [2] as an example. With respect to randomization, each subject was randomly divided into a group performing the prevention training program or a group performing the placebo training program using a stochastic computer-generated method. With respect to allocation concealment, group assignment was performed (according to personal registration number) by the head nurse who maintained the allocation sequence and who otherwise did not participate in the study. With respect to masking, the subjects and program instructors did not know which of the training programs was being tested. All subjects with knee or shin pain were examined by one of the authors who was blinded to training group allocation. Data were entered in a blinded manner from coded collection forms.

In light of these actual methods, we are interested in comments and direction from Dr. Berger on how to better design, conduct, and report randomization, allocation concealment, and masking in future orthopaedic prevention studies.

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