Is it Time for Sports Performance Researchers to Adopt a Clinical-Type Research Framework?

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For this editorial, my invited co-authors and I would like to highlight a manuscript in this issue of Int J Sports Med entitled “The effects of exercise upon symptoms and quality of life in patients diagnosed with irritable bowel syndrome: a randomised controlled trial” [5]. Not only do the authors address an interesting and important research question, but they also provide a reasonable template for anyone who might be contemplating a randomised controlled trial in the sport and exercise sciences.

The study by Daley et al. [5] is obviously more relevant to human health than to sports performance. Health researchers and clinicians have worked hard over the last 20 years to set down gold-standard research practices and methods for other researchers to adopt. For example, there is a logical and accepted “roadmap” in clinical research governing how a particular treatment or intervention should be examined for efficacy and effectiveness. Efficacy is a measure of the ability of a treatment to improve whatever condition it is indicated for, whereas effectiveness is a measure of how well a treatment works in the “real world” with the target population [6]. To cite an example that is relevant to sports performance, it is known that some substances (e.g., sodium bicarbonate) are efficacious in manipulating the acid-base balance during repeated bouts of intense exercise [4]. Nevertheless, the effectiveness of these substances for improving real athletic performance might be less clear due to the potential for inducing gastrointestinal disturbances. The exploration of issues like efficacy and effectiveness is inherent within the “phased” framework for clinical trials [12].

Alongside this framework, there are also published regulations covering how an individual randomised controlled trial should be managed and reported in a scientific journal. These regulations are laid down in the so-called “CONSORT” statement, which can be found at: http://www.consort-statement.org/.

We delimit this editorial to any study in which the primary variable is performance (or some component of athletic performance) and the research participants are competitive athletes. It is clear that there are sound studies published in the literature of this type and, in this editorial, we are able to cite some examples which have been published in past issues of Int J Sports Med. Nevertheless, we are unaware of any parallel procedures to phased clinical trials and the CONSORT statement, which have been set down by sports performance researchers to formalise the evidence-based research process. There are probably good reasons, which need to be considered, for this apparent difference between sports performance and clinical research methods. Hopefully, this editorial will help to initiate discussions at future conferences and workshops about whether such a framework is desirable for sports performance researchers and what form it might take.

The Clinical Research Framework

A clinical treatment is conventionally explored over 4 designated phases; I, II, III and IV (an additional “phase 0” trial is a relatively recent development). Nevertheless, even before these clinical phases are adopted, so-called “preclinical studies” can be administered which usually involve animal models or in vitro investigations to ascertain preliminary usefulness and toxicity of a proposed treatment. This preclinical phase might not have a direct analogy in sports performance research. It might be unethical to involve animals in research (especially if these animals are sacrificed) in order to help humans win athletic competitions. Nevertheless, there could be some crossover which can be identified between preclinical trials of interventions designed to ameliorate impaired muscle function in diseased animal models to the exercise performance of healthy individuals.

Phase 0 trials
These trials might involve 10–15 healthy human participants (not necessary the target population; e.g., not athletes) who are administered a small dose of the treatment over a short period of time (e.g., 7 days) to check that the biological effects which are elicited are as predicted by the preclinical trials. There might not necessarily be a comparator (control) group involved in this trial. It is fair to say that adverse effects of interventions designed to improve sports performance are probably less likely (although not unknown) than for drug trials in clinical medicine. In a sports performance context, a researcher might administer a small amount of a nutritional aid, or a specific training regimen, to a small sample of participants and measure a biological outcome in order to confirm that the intervention is biologically active and has the potential to improve real athletic performance.

The study needs to be extremely detailed and it is even suggested particularly in concealing the allocation sequence from those assessing the intervention outcomes. The CONSORT statement covers randomisation procedures, especially in terms of blinded data analysis and concealment issues might be even more detailed. This point illustrates the difficulty in executing the “perfect” randomised controlled trial. Our main point is that, without clear guidelines for such trials in a sports performance context, it is difficult to judge the validity of some studies on interventions for athletic performance.

Phase II trials
In these trials, the treatment is administered to larger groups of individuals. These trials are usually of the randomised controlled type on patients with the target disease. This phase is critical in the intervention research process. An analogy would be a proper randomised controlled trial involving the intended target population (e.g., elite athletes). Many health-related studies involving physical activity interventions, such as that by Daley et al. [5] are randomised controlled trials. Such trials have also been attempted in the context of sports performance. For example, in a recent study on, in part, cycle endurance capacity, Burgomaster et al. [3] assigned 16 participants to either an interval training group or a control group. Endurance capacity was found to increase by 100%, on average, for the intervention participants who performed a total of only 15 min of cycling over a two-week period. In a subsequent letter to the editor [8], the design of this study was discussed in terms of the participant allocation methods and the possible influence of human reactivity effects. Many aspects of the CONSORT statement centre on the control of such effects in a phase II randomised controlled trial.

The CONSORT statement covers randomisation procedures, especially in concealing the allocation sequence from those assessing eligibility of participants. How participants are enrolled in the study needs to be extremely detailed and it is even suggested that a third party should be responsible solely for management of this component of the study. Sample sizes at each stage of the trial should be transparent. Primary and secondary outcomes should be clearly identified. It is also advised that a statistician, who has no knowledge about what the study entails, is recruited. The data should be presented anonymously to this person for analysis. Daley et al. [5] adhere to many of the guidelines in the CONSORT statement, although each researchers role, especially in terms of blinded data analysis and concealment issues might have been more detailed. This point illustrates the difficulty in executing the “perfect” randomised controlled trial. Our main point is that, without clear guidelines for such trials in a sports performance context, it is difficult to judge the validity of some studies on interventions for athletic performance.

Phase III trials
These trials can involve hundreds or even thousands of participants and, therefore, might be administered across multiple research groups in a so-called multicentre approach. Meta-analytic procedures might also be applied to examine the pooled effects of a certain intervention across several published studies. Such procedures basically improve the precision of estimation of how effective the treatment is. A multicentre approach could be an exciting new way in which interventions are examined in sports performance research, although there might be political or competitive hurdles to overcome. Meta-analyses, which are relatively rare in a sports performance context, might become very important in view of how difficult it is to recruit a reasonable number of elite athletes in any one study. Health-related analyses of existing study findings are, again, administered according to set-down procedures, such as those communicated in the Cochrane handbook for systematic reviews (http://www.cochrane.org/resources/handbook/) and the QUORUM statement for meta-analytic procedures [11].

Phase IV trials
These trials are basically post-marketing surveillance trials designed to monitor the treatments once they are available for use. Despite the logical process of phased clinical trials, some treatments might be associated with insidious and unpredictable side-effects which might only become apparent after years of use. These trials are usually epidemiological in nature.

In conclusion, there is overwhelming evidence that the introduction of rigorous regulations like the CONSORT statement have improved the quality of randomised controlled trials in a clinical
In our opinion, it is now time for sports performance researchers to consider a similar formal approach to examining interventions for athletic performance. In Table 1, we present a framework for such an approach. We highlight the fact that for many of the suggested phases to be adopted, agreement and collaboration between researchers and deliverers of applied intervention is required. We look forward to the future when researchers have met and agreed on a set of procedures that can be adopted for confidence in the evidence base in sports performance research.

References