

WHO RESPONDS TO A PLACEBO? FACTORS ASSOCIATED WITH RESPONSE TO PLACEBO DURING A DOUBLE-BLIND, RANDOMISED CONTROLLED TRIAL

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INTRODUCTION:

The placebo effect, a desirable outcome resulting from a person's expected and/or learned response to a treatment or situation, may significantly influence the interpretation of double-blind, randomised controlled trials (RCT). High placebo responder rates may under-estimate the true efficacy of a treatment. It is therefore important for researchers conducting RCTs to be cognisant of factors influencing the placebo response. In this study, we performed a retrospective analysis of a RCT of participants' response to placebo beetroot juice on 5-km running performance.

METHODS:

Participants were 70 recreational runners (male 51.2%; mean \pm SD = age = 32.0 \pm 10.4 years, hours per week training = 6.16 \pm 3.98, 5-km personal best = 24:28 minutes:seconds). After completing measures of sport supplement use and their beliefs about sport supplements, participants completed 5-km time-trials at baseline and with the ingestion of nitrate depleted placebo (containing \sim 0.04 mmol of nitrate, Beet It Sport[®]). The smallest worthwhile change was calculated to identify placebo responders and backward linear regression identified variables associated with the placebo response.

RESULTS:

Nearly two-thirds of participants were identified as placebo responders (63%). Compared to baseline, time to run 5-km among placebo responders was 2.76 \pm 0.36%, whereas for non-responders it was -1.45 \pm 0.46%. Sport supplement use (β = -2.162, p = 0.042), sport supplement beliefs (β = -0.712, p = 0.034) and being male (β = -2.030, p = 0.022) predicted the response to placebo. Stronger beliefs about sport supplements also influenced the magnitude of improvement in 5-km times in the placebo condition compared to baseline (β = 0.820, p = 0.028).

CONCLUSION:

Results demonstrate that participants recruited to a RCT of beetroot juice on 5-km running performance were more likely to respond to a placebo if they used sport supplements, reported strong beliefs in their effectiveness and were male. Given that interpretation of RCTs can be influenced by the placebo effect, researchers using these research designs should consider measuring and controlling for these variables in their analyses. Further data on what may influence the response to a placebo is needed to help inform interpretation of RCTs.