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Validation of a Placebo Method with Potential for Blinding in Ultrasound-Guided Dry Needling

Authors : Johnson C. Y. Pang, Bo Pengb, Kara K. L. Reevesc, Allan C. L. Fud

Abstract : Objective: Dry needling (DN) has long been used as a treatment method for various musculoskeletal pain conditions. However, the evidence level of the studies was low due to the limitations of the methodology. Lack of randomization and inappropriate blinding are potentially the main sources of bias. A method that can differentiate clinical results due to the targeted experimental procedure from its placebo effect is needed to enhance the validity of the trial. Therefore, this study aimed to validate the method as a placebo ultrasound(US)-guided DN for patients with knee osteoarthritis (KOA). Design: This is a randomized controlled trial (RCT). Ninety subjects (25 males and 65 females) aged between 51 and 80 (61.26±5.57) with radiological KOA were recruited and randomly assigned into three groups with a computer program. Group 1 (G1) received real US-guided DN, Group 2 (G2) received placebo US-guided DN, and Group 3 (G3) was the control group. Both G1 and G2 subjects received the same procedure of US-guided DN, except the US monitor was turned off in G2, blinding the G2 subjects to the incorporation of faux US guidance. This arrangement created the placebo effect intended to permit comparison of their results to those who received actual US-guided DN. Outcome measures, including the visual analog scale (VAS) and Knee injury and Osteoarthritis Outcome Score (KOOS) subscales of pain, symptoms and quality of life (QOL), were analyzed by repeated-measures analysis of covariance (ANCOVA) for time effects and group effects. The data regarding the perception of receiving real US-guided DN or placebo US-guided DN were analyzed by the chi-squared test. The missing data were analyzed with the intention-to-treat (ITT) approach if more than 5% of the data were missing. Results: The placebo US-guided DN (G2) subjects had the same perceptions as the use of real US guidance in the advancement of DN ($p<0.128$). G1 had significantly higher pain reduction (VAS and KOOS-pain) than G2 and G3 at 8 weeks (both $p<0.05$) only. There was no significant difference between G2 and G3 at 8 weeks (both $p>0.05$). Conclusion: The method with the US monitor turned off during the application of DN is credible for blinding the participants and allowing researchers to incorporate faux US guidance. The validated placebo US-guided DN technique can aid in investigations of the effects of US-guided DN with short-term effects of pain reduction for patients with KOA. Acknowledgment: This work was supported by the Caritas Institute of Higher Education [grant number IDG200101].

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