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Study Protocol

Effects of laying on of hands with and without a spiritual context on pain and functionality of older women with knee osteoarthritis: study protocol for a randomized controlled trial

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ABSTRACT

BACKGROUND: Laying on of hands (LooH) is a culturally-accepted therapy in several traditions. In Brazil, “Spiritism” (third-largest religious tradition in number of followers) uses LooH with the name of “Spiritist *Passe*” (SP). However, there are few studies assessing SP’s role in medical outcomes. The present study aims to investigate the effects of LooH, with and without a spiritual context, on pain, joint stiffness, and functional capacity of older women (≥ 60 years old) with knee osteoarthritis (KOA).

METHODS/DESIGN: In this triple-blind, prospective randomized controlled trial, older women with KOA are assigned to three groups: LooH with a spiritual context group, LooH group without a spiritual context, and a control group receiving no intervention. Patients are assessed by a blinded researcher at baseline, 8 weeks, and 16 weeks. Pain, joint stiffness, and functional capacity are assessed using Western Ontario and McMaster Universities Osteoarthritis Index. Other measures such as anxiety, depression, gait speed, and quality of life will also be assessed. To detect differences between groups, a post-intervention comparison between the three groups and a mean change (post-pre) comparison among the three groups will be done using analysis of variance. All statistical analyses will be performed using an intention-to-treat approach and a per-protocol analysis.

DISCUSSION: A pragmatic design using SP, LooH without spiritual context, and no LooH may provide further scientific evidence on SP’s feasibility and efficacy for KOA patients.

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