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Effect of laying on of hands as a complementary therapy for pain and functioning in older women with knee osteoarthritis: A randomized controlled clinical trial

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Abstract

Aim: To assess the effects of laying on of hands (LooH) as a complementary therapy to kinesiotherapy, on pain, joint stiffness, and functional capacity of older women with knee osteoarthritis (KOA) compared to a control group.

Methods: In this randomized controlled clinical trial, participants were assigned into 3 groups: LooH with a spiritual component ("Spiritist passe" Group - SPG), LooH without a spiritual component (LooH Group - LHG), and a control group receiving no complementary intervention (Control Group - CG). Patients were assessed at baseline, 8 weeks, and 16 weeks. Primary outcomes were joint stiffness and functional capacity (Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC]), and pain (WOMAC and visual analog scale). Secondary outcomes were anxiety, depression, mobility, and quality of life. Differences between groups were evaluated using an intention-to-treat approach.

Results: A total of 120 women (mean age = 69.2 ± 5.2 years) with KOA were randomized (40 participants per group). At 8 weeks, SPG differed significantly from the LHG for WOMAC Functional Status (between-group difference in the change = 0.97; 95% CI: 0.35 to 1.59, P = .001); Anxiety levels (between-group difference in the change = 1.38; 95% CI: 0.11 to 2.65, P = .027); and also from the CG for all outcomes with exception of WOMAC Stiffness. After 16 weeks, SPG differed significantly from the LHG only for WOMAC Functional Status (between-group difference in the change = 0.92; 95% CI: 0.32 to 1.52, P = .001]) and also from the CG for all outcomes with exception of WOMAC Stiffness and timed up-and-go.

Conclusion: Our results suggest that LooH with a "spiritual component" may promote better long-term functional outcomes than both LooH without a "spiritual component" and a control group without LooH.

Trial registration: ClinicalTrials.gov Identifier NCT02917356.

KEYWORDS
complementary therapies, holistic therapies, knee osteoarthritis, spiritual healing, spiritual therapies, therapeutic touch

1 | INTRODUCTION

Osteoarthritis (OA) is a multifactorial progressive disease that is more prevalent in older women, where the knee is the weight-bearing joint most affected by the condition.[1] Because knee OA (KOA) results in pain and disability which cause a decline in work and social functioning, the condition may contribute to mental health problems[2] and negatively impact quality of life (QoL).[3] There is a vast array of options for treating this condition, including kinesiotherapy, recognized as one of the most important non-pharmacological therapies for KOA by many organizations, such as the Osteoarthritis Research Society International (OARSI), The European League Against Rheumatism (EULAR), National Institute for Health and Care Excellence (NICE) and The American College of Rheumatology (ACR).[4-7]

Although kinesiotherapy and other physical therapy and medical approaches for OA can be beneficial, their efficacy remains limited. Due to these limitations, a large contingent of patients seeks complementary and alternative medicine (CAM) therapies for the treatment of OA.[8] CAMs are a group of medical and healthcare systems, practices and products, which are not considered to be part of conventional medicine.[9]

The focus of the present study is the laying on of hands (LooH) CAM therapy. LooH is defined as the use of hands on or near the body to help in the "healing" of diseases.[10] The mechanisms for such therapy are not well elucidated; however, some theories hypothesize that the human body is composed of "energy fields", and according to this theory, the patient could exchange energy with the healers, even without physical contact.[10] LooH is a CAM used throughout the world, among different cultures and religions and includes: Reiki, Johrei and external *Qigong*, bioenergy, contemporary metaphysical tradition and, Therapeutic Touch and Healing Touch, where the latter are used by Western healthcare professions, mainly in the nursing context.[11] Although LooH can be provided in several different ways, the technique is usually delivered as follows: the "healer" prepares him/herself to administer the technique (ie, centering to a calm, quiet and balanced condition), attunes to an energy, moves hands with the palms facing toward the patient and at a distance of about 1-2 inches over the body of the patient in a smooth movement with the intention to "heal".[12] Studies have investigated the effect of LooH in KOA patients, demonstrating positive effects of external *Qigong*, Healing Touch and Therapeutic Touch on pain, functioning, mobility, joint stiffness, muscle strength, depression, and mood.[13-17]

LooH is also used in the tradition of Spiritism, the third-largest religion in Brazil. LooH is referred to as "Spiritist Passe" (SP) in this tradition and is part of the therapies practiced free of charge under Spiritism.[18] The SP is defined as "energy transfusion, derived from the Spiritist healer and from good Spirits, or a combination of both, that changes the cell field".[19] Therefore, this tradition is supposed to have a "spiritual component", in which an alleged "spiritual energy" would act in the patient in addition to the energy provided by the healer. It is estimated that there are 1650 Spiritist centers offering SP in Brazil and these centers receive individuals from all religious backgrounds. A previous study investigating 55 Spiritist centers in São Paulo, Brazil found that these centers receive approximately 60 000 attendees per month and that SP is offered in all of these centers.[20]

Concerning the scientific background of SP, the first study published on this subject was an experiment demonstrating that SP was able to inhibit bacterial growth in vitro.[21] Subsequently, some clinical trials evaluated SP, finding that participants who received SP showed reduced anxiety and depressive symptoms, negative effects and muscle tension, as well as improvements in QoL, immunological response, peripheral oxyhemoglobin saturation and well-being.[22-27]

Despite this promising evidence, these studies have limitations that require caution when interpreting their results. Most trials have not evaluated SP provider characteristics, the control groups did not have the intention to "heal the patient", these studies involved only a small number of intervention sessions and short follow-up periods, and lacked an intention-to-treat (ITT) analysis. Finally, to our knowledge, there are no studies investigating differences in outcomes between LooH with a "spiritual component" and LooH using a more secular approach.

Therefore, the aim of this study was to assess the effects of LooH (with and without a spiritual component), as a complementary therapy to kinesiotherapy, on pain, joint stiffness, and functional capacity of older women (60 years old) with KOA compared to a control group. As a secondary objective, levels of QoL, and depression and anxiety symptoms, were also compared for the 3 intervention arms of the study.

2 | STUDY DESIGN AND METHODS

This is a triple-blind (ie, blinded assessor, patient and statistician), single-center, prospective, parallel and randomized controlled trial, registered on clinicaltrials.gov under number NCT02917356. A full detailed description of the methods for this trial can be found in a previous publication.[28] This study was approved by the Research Ethics Committee of the Federal University of Juiz de Fora, Brazil under registry CAAE 52 623 115.0.0000.5147.

2.1 | Randomization

Patients were randomly assigned into 3 groups at a 1:1:1 ratio. A researcher, not involved with data collection, randomized the patients

using block randomization procedures (block size = 6) and computer-generated random numbers - List randomizer of permutations (random.org). Participants were allocated into 3 groups: LooH with a spiritual component ("Spiritist Passe Group", SPG), LooH without a spiritual component (Laying on of Hands Group, LHG) and a group without LooH (Control Group, CG).

2.2 | Sample and setting

The sample comprised women with KOA. These participants were recruited using different strategies: advertisement of the study protocol through posters and lectures at the Primary Health Care Units; referrals by health professionals; and by spontaneous demand. The study was carried out in a public health setting in the city of Juiz de Fora, Brazil, where medical, physical therapy and nursing care are provided to patients aged 60 years and older.

2.3 | Eligibility criteria

For inclusion in the study, participants had to be: female; aged 60 years or older; have primary OA in both knees; OA grade II or III according to Kellgren and Lawrence criteria[29]; a Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain score > 5[30]; use stable doses of analgesic or anti-inflammatory drugs during intervention (ie, in each session of the intervention, researchers asked if there was a change in the dose of analgesics in order to identify acute problems and to avoid its influence in the results of the trial. In order to be included, participants were required to maintain the same dosage of analgesics throughout the trial duration); not perform physical exercises, physical therapy or any kind of energy therapy different from those proposed in this study; and be able to read, understand, and speak Portuguese. Exclusion criteria included: use of oral, systemic injectable or intra-articular steroids in the 3 months leading up to study screening; use of intra-articular hyaluronate in the 3 months leading up to study screening; previous hip or knee arthroplasty; presence of neurological diseases or other rheumatic diseases; report other causes of pain in lower limbs; have medical contraindications for light-to-moderate physical activity and; have cognitive impairment, as assessed by the Mini-Mental State Examination.[31]

2.4 | Procedure

The patients, the researcher who enrolled the participants, the physical therapists who provided the kinesiotherapy, the outcome assessor, and the researcher conducting statistical analyses were all blinded to treatment assignment. The blinding of patients was done using swimming goggles (Master Beach Black®) painted black (Spray Mundial Prime®) and patients were wearing black goggles while receiving the CAM therapy (ie, "Spiritist Passe Group", LooH without a spiritual component or no LooH), but not while receiving physical therapy.

2.4.1 | Kinesiotherapy program

Patients enrolled in all groups participated in a 45-minute, light-to-moderate group kinesiotherapy program consisting of 5-minute warm-up and stretching, 37-minute exercise (strengthening of lower limbs and neuromotor exercise - motor skills and balance), and 3-minute relaxation (detailed description in Zacaron et al[28]). The intervention took place twice a week for 8 weeks and was supervised by 6 trained physical therapists blinded to treatment assignment. Perceived exertion during kinesiotherapy was measured using the revised Borg Scale (0-10) after each session.[32]

2.4.2 | Complementary interventions

During the sessions for all 3 groups, patients remained seated and received the following verbal command: "Relax and calm your mind". All groups received treatment simultaneously in different dimly lit rooms, which were rotated daily. The interventions were applied without touching the patients, for 5 minutes once a week (8 weeks of intervention). The SPG received SP, applied after kinesiotherapy, and SP providers were oriented to think about "healing the patient". The LHG received LooH (with no spiritual component), applied after the kinesiotherapy, and LooH providers were oriented to think about "healing the patient". The CG received only kinesiotherapy, but not LooH. To make control patients feel the presence of someone in the room, they were accompanied by volunteers who moved slowly and randomly to simulate the presence of someone performing LooH. However, there was no intention to heal the patient in this group.[28]

2.5 | Measures

Patients were assessed by a blinded researcher at baseline (0 week), post-intervention (8 weeks) and follow-up (16 weeks). During the follow-up period (8-16 weeks), patients were periodically contacted by phone to ensure they had not received additional KOA interventions, where doing so excluded them from the study. Patients were then invited for the final follow-up assessment (16 weeks). All primary and secondary measures were assessed at the same day.

2.5.1 | Sample characteristics

Sociodemographic, clinical, and anthropometric (Filizola® anthropometric scale) data; religiousness (Duke University Religion Index - DUREL),[33] spirituality (Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being Scale - FACIT-Sp 12),[34] optimism (Life Orientation Test-Revised version - LOT-R),[35] and credibility and expectancy about the effect of treatment (section I of Credibility/Expectancy Questionnaire - CEQ)[36] levels were collected to characterize the older women with OA (detailed description in Zacaron et al[28]).

2.5.2 | Primary outcomes

Pain intensity in the knees was assessed using the visual analog scale (VAS) and WOMAC Pain subscale.[30,37] Functional capacity was assessed by the WOMAC functional capacity subscale.[30,37] The WOMAC instrument, validated for use in Brazil, comprises 5 items related to pain, 2 items related to joint stiffness, and 17 items related to functional capacity. Each item was scored from 0 (none) to 10 (extreme). Higher scores represent worse health status.[37] The timeframe for the primary endpoint was defined as both 8 and 16 weeks.

2.5.3 | Secondary outcomes

Anxiety and depression symptoms were assessed using the Hospital Anxiety and Depression Scale (HADS).[38] Functional mobility was evaluated using the timed up-and-go (TUG) test[39] and QoL was determined using the World Health Organization Quality of Life-Bref (WHOQOL-Bref).[40] Perceived changes in symptoms resulting from treatment were recorded on a 5-point Likert scale: worsened, unchanged, slightly improved, much improved, and healed.[41] In order to collect patients' opinions about different aspects of the treatment and on the clinical application of LooH, 5 questions were applied at the 16th week evaluating which group participants believed they were enrolled in, the success of the therapy, and whether LooH should be used as a complementary therapy. The timeframe for the secondary endpoint was defined as both 8 and 16 weeks.

2.5.4 | Intervention staff characteristics

Sociodemographic, dietary and substance use/abuse data (assessment form developed by researchers) and well-being (Subjective Well-being - SWB)[42] information were collected to define the characteristics of SP and LooH providers.

In order to collect the state of physical and mental health of SP and LooH providers, prior to each session, they were asked the following question: "Have you had any bad experiences during the last week that have affected your physical or mental health? (yes or no)".

2.6 | Sample size

Sample size was calculated based on a previous study investigating the effect of therapeutic touch on KOA,[17] and previous studies using the total score for each subscale of the WOMAC instrument.[14,43] The sample size was based on multiple primary outcomes (ie, the trial is successful if there is a significant improvement in at least 1 primary outcome). The minimum required sample was 105 participants for this trial, adopting an alpha of 0.05 and a power (1-Beta) of 0.80. The complete sample size calculation is described in a previous publication.[28]

2.7 | Statistical analysis

Descriptive analysis was performed using frequency, percentage, mean, and standard deviation for all baseline characteristics.

The 3 groups were compared at baseline in terms of their sociodemographics, clinical conditions and instruments, using the Chi-square test for categorical variables and analysis of variance (ANOVA) for independent measurements, using Bonferroni as a post hoc test.

Then, a 3 × 3 repeated-measures multiple analysis of variance - MANOVA (group [LHG, CG, SPG] by time [baseline, 8th week and 16th week]) on the dependent variables WOMAC Pain, WOMAC Stiffness, WOMAC Functional Capacity, VAS, HAD Anxiety, HAD Depression, TUG and WHOQOL-Bref was carried out. If significant, the subsequent post hoc analyses were conducted through Bonferroni post hoc tests.

Finally, the differences between changes in scores for each scale (post – Pretests) between groups were analyzed using ANOVA for independent measurements and Bonferroni as a post hoc test. In case of imbalances, analysis of covariance (ANCOVA) was carried out considering baseline scores.

All statistical analyses were performed using the ITT and the per protocol (PP) approaches. For the PP analysis, patients having missed more than 4 sessions of kinesiotherapy or 2 sessions of CAM therapy were excluded.

A total of 13 patients (out of 120) had their data imputed. Missing data were handled under the assumption of "missing at random" (MAR). The method of Multiple Imputations was used (method "fully conditional specification" – an iterative Markov chain Monte Carlo method available in SPSS) with 10 iterations for every imputation. We imputed the missing values of outcomes at 8 and 16 weeks of follow-up (ie, WOMAC Pain, WOMAC Stiffness, WOMAC Functional Capacity, VAS, HAD Anxiety, HAD Depression, TUG and WHOQOL-Bref) and the following predictors were used in linear regression models in order to estimate the follow-up outcomes: baseline data of all outcomes, age and grade of KOA. At 16 weeks, outcomes assessed at 8 weeks were also used if available.

The Statistical Package for Social Sciences software version 17.0 (IBM Corp, Armonk, NY, USA) was used for the multiple imputation and for all statistical analyses.

3 | RESULTS

The detailed Consolidated Standards for Reporting Trials (CONSORT) diagram depicting the selection process and exclusion and inclusion criteria is given in Figure 1. Of 1082 patients initially invited to participate, 120 were included and randomly assigned into 3 groups (n = 40 per group). During the intervention period, there were withdrawals/ dropouts due to absences (3 in SPG, 4 in LHG and 1 in CG), other treatment (1 in SPG) and goggles intolerance (1 in CG). During the follow-up period, there were withdrawals due to loss of contact (1 in SPG) and other treatment (2 in CG).

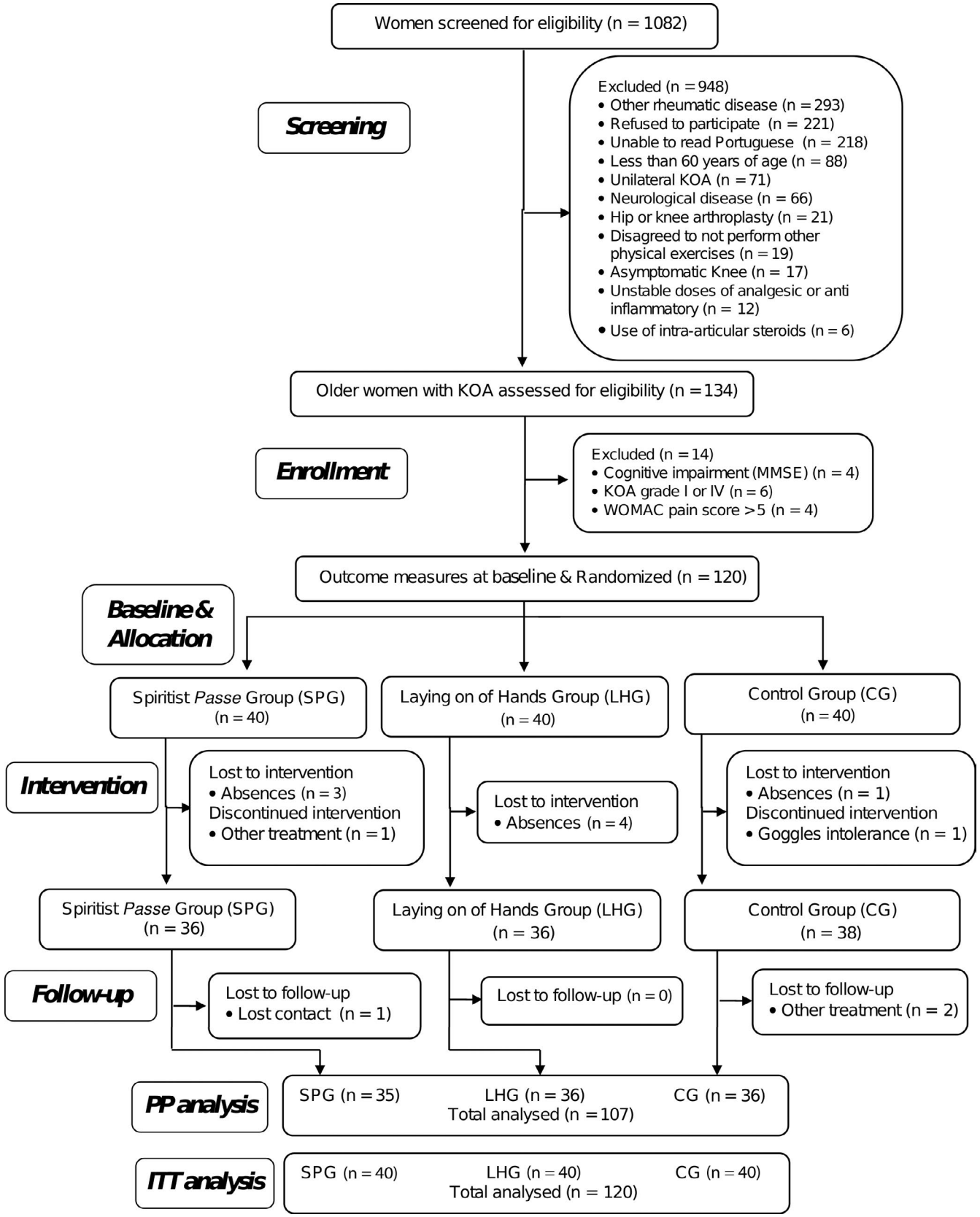

FIGURE 1 Consolidated Standards for Reporting Trials (CONSORT) flow chart. Bars represent 95% confidence intervals. ITT, intention-to-treat; KOA, knee osteoarthritis; MMSE, Mini-Mental State Examination; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index

Therefore, a total of 107 patients completed the study (35 in SPG, 36 in LHG and 36 in CG). However, all 120 randomized patients were included in ITT analysis.

3.1 | Baseline characteristics

3.1.1 | Participants

At baseline, there were no significant differences in relation to the sociodemographic characteristics and clinical conditions and instruments. The study sample comprised women who were elderly, of White ethnicity, had more than 4 years of formal education and were married (Table 1).

3.1.2 | Staff

There were no significant differences in sociodemographic data, dietary status, substance use/abuse or well-being among the SP, LooH providers and volunteers accompanying the control group. Likewise, there were no differences concerning the occurrence of bad experiences among the groups (Table S1).

3.2 | Analyses for the primary and secondary outcomes

Univariate analyses were conducted on each dependent variable as a follow-up test to MANOVA The comparison among groups showed differences for the scores of VAS, WOMAC Pain, WOMAC Functional capacity and Total WHOQOL-Bref.

The follow-up outcomes of the groups are shown in Figures 2 and 3. At 8 weeks, Bonferroni post hoc tests revealed the following differences: (a) VAS-Pain, differences between SPG and CG, and between LHG and CG, but not between SPG and LHG; (b) WOMAC Pain, differences between SPG and LHG, between SPG and CG, and between LHG and CG; and (c) WOMAC Functional Capacity, differences between SPG and CG and SPG and LHG, but not between LHG and CG. There were no differences for the scores of WOMAC Stiffness among groups. In relation to the secondary outcomes, there were significant differences in: (a) HAD Depression, differences between SPG and CG, but not between LHG and CG and LHG and SPG; (b) WHOQOL Total Score, differences between SPG and CG and LHG and CG, but not LHG and SPG. There were no differences for TUG and HAD Anxiety.

At 16 weeks, Bonferroni post hoc tests revealed the following differences: (a) VAS-Pain, differences between SPG and CG, and between LHG and CG, but not between SPG and LHG; (b) WOMAC Pain, differences between CG and LHG, and between SPG and CG, but not for LHG and SPG; and (c) WOMAC Functional Capacity, differences between SPG and CG, and between SPG and LHG, but not between LHG and CG. There were no differences for the scores of WOMAC Stiffness among groups. In relation to the secondary outcomes, there were significant differences in WHOQOL Total Score, differences between SPG and CG and for LHG and CG, but not for LHG and SPG. There were no differences for TUG, HAD Depression and HAD Anxiety.

While investigating the differences between changes in scores for each scale (Table 2) at 8 weeks, SPG differed significantly from the LHG for WOMAC Functional Status (adjusted mean = −2.99, 95% CI: −3.35 to −2.64 vs. −2.02, 95% CI: −2.38 to −1.66; between-group difference in the change = 0.97, 95% CI 0.35 to 1.59, $P = .001$); HAD Anxiety (−3.77, 95% CI:-4.74 to −2.80 vs. −2.39, 95% CI: −3.12 to −1.66; between-group difference in the change = 1.38, 95% CI: 0.11 to 2.65, $P = .027$); and also to the CG for all outcomes with exception of WOMAC Stiffness. After 16 weeks, the difference in change for SPG differed significantly from the LHG only for WOMAC Functional Status (adjusted mean = −2.85, 95% CI: −3.20 to −2.51 vs. −1.93, 95% CI: −2.27 to −1.58; between-group difference in the change = 0.92, 95% CI: 0.32 to 1.52, $P = .001$) and also to the CG for all outcomes with exception of WOMAC Stiffness and TUG.

In the PP analysis, results were maintained for the MANOVA procedure. However, while investigating the differences between changes in scores for each scale there were differences between SPG and LHG in the WOMAC Pain and WOMAC Function. These results can be visualized in the Supplementary material (PP).

3.3 | Other analyses

There was no difference between groups regarding the numbers of kinesiotherapy ($P = .713$) and LooH ($P = .717$) sessions received by each group after 8 weeks of protocol (Table S2). Based on pre- and post-intervention VAS-Pain measures for each CAM session, no adverse effects were observed for SP application and only 2 LHG patients reported a maximum 1-point increase in pain.

Concerning the perceptions and opinions of the participants, most believed LooH should be used to treat OA and depression/anxiety as a complementary therapy. Likewise, most participants believed that health professionals should consider using LooH in clinical settings. These differences were not significant among groups (Table S2).

Finally, most patients believed they had participated in the SPG, as opposed to the CG or LHG. Although there was no significant difference in this perception between groups, only 57.6% of the SPG believed they received Spiritist Passe as compared to 72.7% of the LHG and 71.9% of the CG ($P = .194$), and most felt the interventions had improved their condition (Table S2).

4 | DISCUSSION

The results of the present study suggest that LooH with a “spiritual component” may promote better outcomes than LooH without a “spiritual component” or a control group without LooH. Our results

TABLE 1 Baseline anthropometric, sociodemographic and clinical characteristics of studied groups

	LHG (n = 40)	CG (n = 40)	SPG (n = 40)
	Mean (SD)	Mean (SD)	Mean (SD)
Age, y	68.85 (5.37)	69.45 (4.84)	69.50 (5.68)
Weight, kg	77.18 (15.38)	75.11 (12.92)	75.28 (13.00)
BMI,(kg/m^2	30.40 (5.45)	29.98 (4.60)	30.75 (4.60)
MMSE	27.73 (2.29)	27.78 (2.08)	27.68 (2.48)
DUREL Organizational	2.90 (1.42)	2.28 (1.10)	2.35 (1.25)
DUREL Non-organizational	1.63 (0.80)	1.63 (1.07)	1.65 (1.07)
DUREL Intrinsic	5.13 (1.81)	4.38 (1.48)	4.90 (1.63)
FACIT-Sp12 Peace	10.88 (3.33)	10.80 (3.13)	10.73 (2.93)
FACIT-Sp12 Meaning of life	11.93 (2.24)	11.63 (2.22)	11.90 (2.47)
FACIT-Sp12 Faith	12.30 (2.13)	12.10 (1.99)	11.95 (2.08)
LOT-R Positive	9.13 (1.50)	9.30 (1.13)	8.93 (1.43)
LOT-R Negative	8.35 (1.67)	8.20 (1.57)	8.38 (1.51)
LOT-R Total	17.48 (2.76)	17.50 (2.25)	17.30 (2.56)
VAS	7.23 (1.30)	6.71 (1.34)	6.96 (1.39)
WOMAC Pain	6.77 (1.19)	6.26 (1.25)	6.41 (1.21)
WOMAC Stiffness	2.34 (2.10)	1.68 (2.22)	1.78 (2.26)
WOMAC Functional capacity	6.45 (1.27)	5.84 (1.32)	5.94 (1.40)
TUG, s	13.89 (2.30)	13.01 (2.85)	13.44 (2.40)
HAD Anxiety	8.23 (4.51)	7.78 (3.62)	8.43 (4.44)
HAD Depression	7.70 (4.27)	6.70 (3.42)	6.55 (3.63)
WHOQOL-Bref Total	13.10 (2.39)	13.20 (2.40)	13.30 (2.34)
Treatment Credibility	21.73 (3.35)	21.33 (3.20)	21.40 (3.15)
Treatment Expectancy	76.75 (14.56)	75.50 (12.18)	75.25 (13.77)
	n (%)	n (%)	n (%)
Ethnicity: White	23 (57.5%)	19 (47.5%)	21 (52.5%)
Marital status: married/cohabitating	17 (42.5%)	15 (37.5%)	16 (40.0%)
Religious affiliation			
Catholic	24 (60.0%)	22 (55.0%)	28 (70.0%)
Evangelical/Protestant	7 (17.5%)	9 (22.5%)	7 (17.5%)
Spiritist	2 (5.0%)	7 (17.5%)	2 (5.0%)
Messianic	1 (2.5%)	0 (0.0%)	0 (0.0%)
None, but believe in God	5 (12.5%)	2 (5.0%)	3 (7.5%)
None, and do not believe in God	1 (2.5%)	0 (0.0%)	0 (0.0%)
Schooling, 4 + y	27 (67.5%)	31 (77.5%)	30 (75.0%)
KOA level			
II	4 (10.0%)	7 (17.5%)	7 (17.5%)
III	36 (90.0%)	33 (82.5%)	33 (82.5%)

Abbreviations: LHG, laying on of hands (LooH) without a spiritual component; CG, control; SPG, LooH with a spiritual component (Spiritist Passe); BMI, body mass index; DUREL, Duke University Religion Index; FACIT-Sp12, Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being Scale; LOT-R, Life Orientation Test-Revised; MMSE, Mini-Mental State Examination; VAS, visual analog scale; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index; TUG, timed up-and-go test; HAD, Hospital Anxiety and Depression Scale; WHOQOL-Bref, World Health Organization Quality of Life-Bref; KOA, knee osteoarthritis.

showed that the SPG (which applied SP once a week for 8 weeks) differed significantly from the LHG on 2 primary outcomes of the study (namely, WOMAC Pain and WOMAC functional capacity) and to the CG for virtually all outcomes. The results were maintained after the end of the intervention. These findings add to the current literature and will be discussed below.

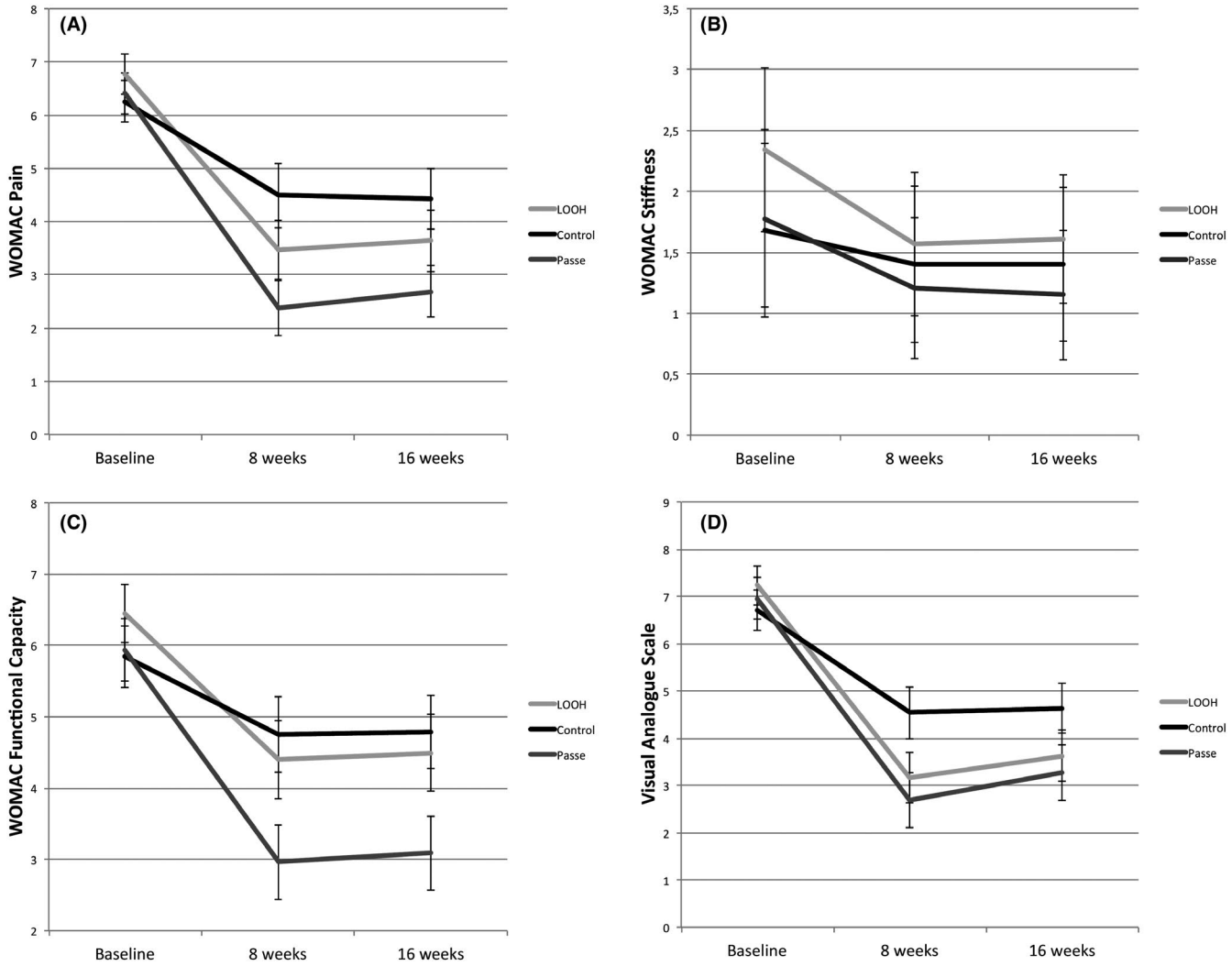

FIGURE 2 Differences among groups for the primary outcomes Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Pain (A), WOMAC Stiffness (B), WOMAC Functional Capacity (C) and visual analog scale pain (D). Bars represent 95% confidence intervals. LooH, laying on of hands without a spiritual component; Passe, laying on of hands with a spiritual component - "Spiritist Passe Group"; Control, group without laying on of hands (Control Group)

In agreement with our results, previous studies on KOA using other LooH approaches, such as therapeutic touch, healing touch or external *Qigong*, reported significant reduction in pain[13,44] and depression,[14] and a significant increase in functional capacity.[13,44] Although there are no studies specifically investigating SP in OA, clinical trials employing SP in patients with various types of health problems have shown promising evidence of reduction in depressive symptoms[22,45] and improvement in QoL.[22,45]

Primary and secondary outcomes were significantly improved between baseline and week 8 in all groups and remained significant between baseline and week 16. The changes in the WOMAC subscales revealed a minimal clinically important difference (MCID) for improvement. A previous study,[46] using WOMAC scale from 0 to 10 (the same used in our study) detected MCID changes of −0.75 for WOMAC Pain (in our study ranging from −1.82 in the CG to −3.71 in the SPG), −0.72 for WOMAC Stiffness (in our study ranging from −0.28 in the CG to −0.76 in the LHG) and 0.67 for WOMAC Function (in our study ranging from −1.05 in the CG to −2.84 in the SPG). Concerning VAS, changes of −1.2 points are considered MCID[47] and in our study this result ranged from −2.16 in the CG to −4.27 in the SPG. Despite the improvements, it is noteworthy that there was a significant difference between applying LooH with and without a "spiritual component" in the primary outcome functional capacity after 8 and 16 weeks. There are several factors that might explain these findings. Some authors suggest that patients submitted to "spiritual healing" may assimilate a "vital energy" passed by the healers and this could be a possible mechanism promoting salutary effects in the mental and physical health of subjects.[27] This has not been scientifically proven and should be interpreted with caution. Another explanation is that patients may have discovered which group they were assigned to and, thus, were more prone to indicate better changes in the group submitted to SP. This seems unlikely in our study, since patients were successfully blinded and the SPG had lowest perception of receiving "spiritual healing". It is also possible that the intention to heal the patient, and

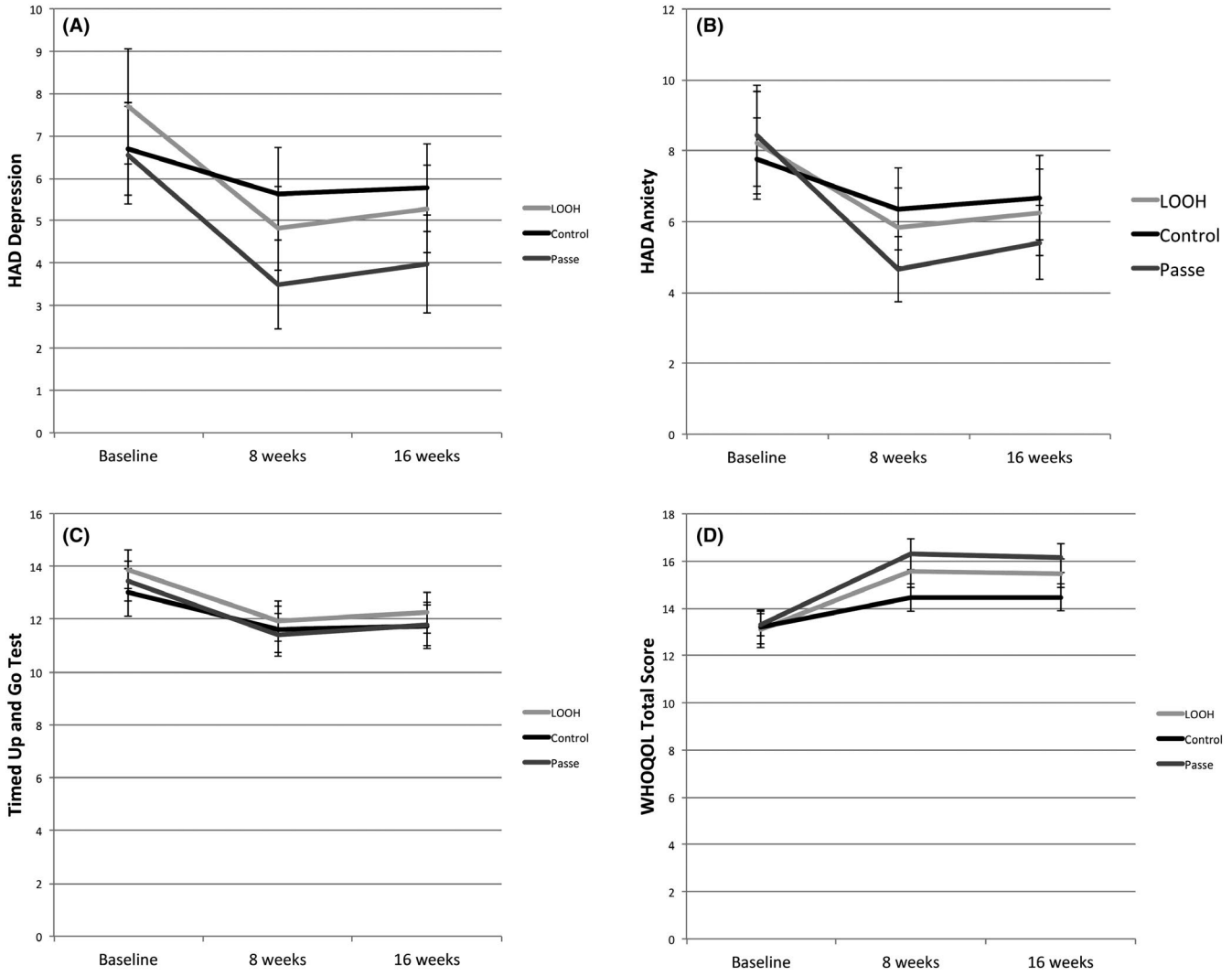

FIGURE 3 Differences among groups for the secondary outcomes Hospital Anxiety and Depression Scale (HAD) Depression (A), HAD Anxiety (B), timed up-and-go test (C) and World Health Organization Quality of Life-Bref (WHOQOL-Bref) (D). Bars representing 95% confidence intervals. LooH, laying on of hands without a spiritual component; Passe, laying on of hands with a spiritual component - "Spiritist Passe Group"; Control, group without laying on of hands (Control Group)

not a "spiritual power", was responsible for these outcomes. Although this is a controversial topic, a previous meta-analysis[48] showed that only having an intention to heal someone was associated with better health outcomes. Likewise, several studies have shown that secular types of LooH, such as therapeutic touch, might be associated with better outcomes relative to control groups.[13-17] In order to minimize this problem, the present study included a control group without "intention to heal", along with another group that had "intention to heal" without a "spiritual connection". Interestingly, even when the SPG and LHG had the same intention to heal the patient, the results were still different between groups. It is unclear whether the level of concentration or training among Spiritist healers was higher than laypersons and, in some way, this could have impacted our results. Since both groups had the same sociodemographic characteristics, other differences concerning age, gender and emotional status seem not to be responsible for these outcomes. Future studies should compare "spiritual healers" against therapeutic touch providers.

Despite the positive results, in the present trial, no evidence was found that the SPG was superior to other groups in relation to mobility (measured by the TUG) and knee stiffness. Our explanation for these negative findings is that the TUG may be not an appropriately responsive performance-based test to assess patients with moderate-to-severe pain due to the transition between sit-to-stand and the short distance used in this measure.[49,50] There also may have been a "floor effect" for the stiffness measure, since this symptom was low in most patients.

The present study has some limitations that should be considered when evaluating the results. First, the absence of patients who were male, younger, with secondary KOA and grades I and IV, limits the generalizability of these findings. Second, although the researchers asked the participants not to switch medication during the study period, it is not possible to guarantee that patients adhered to this recommendation, which may influence one group more than another. Third, although the randomization may

TABLE 2 Between-group differences in change in outcome measures over time

	Group				
	LHG (n = 40)	CG (n = 40)	SPG (n = 40)		Between-group differences in change
Variable	Mean (SD) [95% CI]	Mean (SD) [95% CI]	Mean (SD) [95% CI]	*P*	Mean [95% CI], (*P* value)
VAS[a] (8 weeks – Baseline)	-4.07 (1.28) [−4.48 to −3.65]	-2.16 (1.31) [−2.58 to −1.74]	-4.27 (1.81) [−4.85 to −3.69]	**<.001**	LHG × CG: −1.91 [−2.71 to −1.09] (*P* < .001), LHG × SPG: 0.20 [−0.60 to 1.00] (*P* > .999), CG × SPG: 2.11 [1.29 to 2.91] (*P*< .001)
VAS[a] (16 weeks – Baseline)	-3.60 (1.20) [−3.98 to −3.21]	-2.06 (1.36) [−2.50 to −1.62]	-3.69 (1.74) [−4.25 to −3.13]	**<.001**	LHG × CG: −1.53 [−2.33 to −0.74] (*P* < .001), LHG × SPG: 0.09 [−0.70 to 0.88] (*P* > .999), CG × SPG: 1.63 [0.83 to 2.42] (*P* < .001)
WOMAC Pain[a] (8 weeks – Baseline)	-3.30 (1.09) [−3.65 to −2.95]	-1.77 (1.28) [−2.18 to −1.35]	-4.02 (1.76) [−4.59 to −3.46]	**<.001**	LHG × CG: −1.53 [−2.29 to −0.76] (*P* < .001), LHG × SPG: 0.72 [−0.03 to 1.49] (*P* = .068), CG × SPG: 2.25 [1.49 to 3.02] (*P* < .001)
WOMAC Pain[a] (16 weeks – Baseline)	-3.13 (1.00) [−3.45 to −2.81]	-1.82 (1.19) [−2.20 to −1.44]	-3.71 (1.53) [−4.20 to −3.22]	**<.001**	LHG × CG: −1.31 [−1.99 to −0.62] (*P* < .001), LHG × SPG: 0.58 [−0.10 to 1.26] (*P* = .125), CG × SPG: 1.89 [1.20 to 2.57] (*P* < .001)
WOMAC Stiffness[b] (8 weeks – Baseline)	-0.67 (0.98) [−0.92 to −0.43]	-0.33 (0.67) [−0.58 to −0.09]	-0.60 (1.01) [−0.84 to −0.35]	.128	LHG × CG: −0.34 [−0.085 to 0.765] (*P* = .164), LHG × SPG: −0.07 [−0.49 to 0.35] (*P* > .999), CG × SPG: 0.27 [−0.157 to 0.687] (*P* = .389)
WOMAC Stiffness[b] (16 weeks – Baseline)	-0.74 (0.96) [−1.05 to −0.42]	-0.28 (0.77) [−0.59 to −0.03]	-0.62 (1.19) [−0.93 to −0.31]	.163	LHG × CG: −0.46 [−1.01 to 0.09] (*P* = .134), LHG × SPG: −0.12 [−0.664 to 0.433] (*P* > .999), CG × SPG: 0.34 [−0.88 to 0.19] (*P* = .374)
WOMAC Functional capacity[b] (8 weeks – Baseline)	-2.02 (0.93) [−2.38 to −1.66]	-1.10 (0.89) [−1.46 to −0.74]	-2.99 (1.47) [−3.35 to −2.64]	**<.001**	LHG × CG: −0.92 [−1.54 to −0.29] (*P* = .002), LHG × SPG: 0.97 [0.35 to 1.59] (*P* = .001), CG × SPG: −1.89 [−2.50 to −1.28] (*P* < .001)
WOMAC Functional capacity[b] (16 weeks – Baseline)	-1.93 (0.84) [−2.27 to −1.58]	-1.07 (0.86) [−1.41 to −0.73]	-2.85 (1.44) [−3.20 to −2.51]	**<.001**	LHG × CG: −0.86 [−1.45 to −0.254] (*P* = .002), LHG × SPG: 0.92 [0.32 to 1.52] (*P* = .001), CG × SPG: 1.78 [1.19 to 2.37] (*P* < .001)
TUG, s[a] (8 weeks – Baseline)	-1.95 (0.61) [−2.15 to −1.76]	-1.39 (0.60) [−1.59 to −1.20]	-2.03 (0.80) [−2.29 to −1.77]	**<.001**	LHG × CG: −0.56 [−0.92 to −0.18] (*P* = .001), LHG × SPG: 0.08 [−0.29 to 0.44] (*P* > .999), CG × SPG: 0.64 [0.26 to 1.00] (*P* < .001)
TUG, s[a] (16 weeks – Baseline)	-1.65 (0.73) [−1.88 to −1.41]	-1.25 (0.69) [−1;47 to −1.03]	-1.65 (0.79) [−1.91 to −1.40]	**.024**	LHG × CG: −0.40 [−0.79 to 0.01] (*P* = .056), LHG × SPG: 0.01 [−0.39 to 0.40] (*P* > .999), CG × SPG: 0.40 [−0.01 to 0.80] (*P* = .052)
HAD Anxiety[a] (8 weeks – Baseline)	-2.39 (2.28) [−3.12 to −1.66]	-1.42 (1.40) [−1.87 to −0.98]	-3.77 (3.03) [−4.74 to −2.80]	**<.001**	LHG × CG: −0.97 [−2.23 to 0.30] (*P* = .203), LHG × SPG: 1.38 [0.11 to 2.65] (*P* = .027), CG × SPG: 2.35 [1.08 to 3.61] (*P* < .001)
HAD Anxiety[a] (16 weeks – Baseline)	-1.96 (2.19) [−2.66 to −1.26]	-1.09 (1.51) [−1.58 to −0.60]	-3.01 (2.97) [−3.96 to −2.05]	**.001**	LHG × CG: −0.87 [−2.12 to 0.38] (*P* = .282), LHG × SPG: 1.05 [−0.21 to 2.29] (*P* = .137), CG × SPG: 1.92 [0.66 to 3.16] (*P* = .001)

(Continues)

TABLE 2 (Continued)

Variable	Group				
	LHG (n = 40)	CG (n = 40)	SPG (n = 40)		Between-group differences in change
	Mean (SD) [95% CI]	Mean (SD) [95% CI]	Mean (SD) [95% CI]	*P*	Mean [95% CI], (*P* value)
HAD Depression[a] (8 weeks – Baseline)	-2.88 (2.40) [−3.65 to −2.11]	-1.08 (1.32) [−1.50 to −0.65]	-3.05 (2.17) [−3.75 to −2.36]	**<.001**	LHG × CG: −1.80 [−2.89 to −0.69] (*P* = .001), LHG × SPG: 0.17 [−0.92 to 1.27] (*P* > .999), CG × SPG: 1.97 [0.87 to 3.07] (*P* < .001)
HAD Depression[a] (16 weeks – Baseline)	-2.41 (2.77) [−3.29 to −1.52]	-0.91 (1.24) [−1.31 to −0.51]	-2.57 (2.33) [−3.31 to −1.82]	**.002**	LHG × CG: −1.50 [−2.70 to −0.27] (*P* = .009), LHG × SPG: 0.16 [−1.04 to 1.36] (*P* > .999), CG × SPG: 1.66 [0.45 to 2.86] (*P* = .003)
WHOQOL-Bref Global[a] (8 weeks – Baseline)	2.47 (1.49) [1.99 to 2.94]	1.26 (1.33) [0.83 to 1.68]	2.69 (2.07) [2,03 to 3.35]	**<.001**	LHG × CG: 1.21 [0.30 to 2.17] (*P* = .004), LHG × SPG: −0.22 [−1.16 to 0.72] (*P* > .999), CG × SPG: −1.43 [−2.39 to −0.53] (*P* = .001)
WHOQOL-Bref Global[a] (16 weeks – Baseline)	2.38 (1.54) [1.89 to 2.87]	1.26 (1.41) [0.80 to 1.71]	2.52 (2.13) [1.83 to 3.20]	**.002**	LHG × CG: 1.12 [0.18 to 2.06] (*P* = .013), LHG × SPG:-0.14 [−1.07 to 0.79] (*P* > .999), CG × SPG: −1.26 [0.32 to 2.19] (*P* = .004)

Abbreviations: LHG, laying on of hands (LooH) without spiritual component; CG, control; SPG, LooH with spiritual component (Spiritist Passe); BMI, body mass index; CAM, complementary and alternative medicine; VAS, visual analog scale; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index; TUG, timed up-and-go test; HAD, Hospital Anxiety and Depression Scale; WHOQOL-Bref: World Health Organization Quality of Life-Bref.

[a]Analysis of variance

[b]Adjusted means using analysis of covariance with baseline scores of WOMAC Stiffness and Functional capacity as covariates.

Bold values are indicates p<0.05.

have minimized this problem, it was not possible to achieve a totally homogeneous group in terms of medical comorbidities and medications in use. Fourth, it was not possible to blind SP and LooH providers to the treatment they were giving. Fifth, the same kinesiotherapy program was offered to all patients, despite the fact that OA may present differently and individualized treatment is always desirable. Sixth, although the different effect on function scores between the SPG and LHG groups is supposed to be due to a "spiritual connection", no difference was observed for the majority of other primary outcomes. The fact that this finding was due to chance cannot be excluded. Finally, adverse effects were determined only by an increase in pain or complaints by participants during each kinesiotherapy and CAM session, where this may have led to underestimation of other adverse effects.

The strengths of this study include the randomized controlled design with attention to key methodological features, avoiding confounding factors and compliance with the CONSORT checklist. Moreover, the similarity of the groups at study baseline demonstrates the success of the randomization process. The assessment of quality of the blinding found no difference in guessing the treatment conditions among the 3 groups. The dropout/withdrawal rate was low and similar for all groups, indicating that subjects were committed to remaining in the study. Unlike other CAM and SP trials,[13-17,22-27] our study used an ITT analysis, providing more solid evidence. Finally, the present study added to the current scientific literature, comparing the so-called "spiritual healing" therapies with other interventions.

Although CAM therapies are often rejected because of a lack of belief in their theory, our positive findings could have implications for clinical practice in KOA, mainly due to the low risk of adverse effects compared to those caused by current pharmacological modalities (eg, nonsteroidal anti-inflammatory drugs) and given the low cost of and easy access to CAM therapies. In the case of LooH interventions, as reported previously, there are several ways to provide them to patients according to the type of LooH. For instance, Therapeutic Touch is a non-religious technique used by nurses and other healthcare professionals and is available through certificate programs around the world, ranging from a few hours to more than a year of training.[51] Other techniques, such as Johrei and SP, are related to religious practices and, for this reason, the training is available only to members of these religious traditions.

Future research should include different sample characteristics, combining other physical therapy modalities, such as the 6-minute walk test to assess functional mobility,[50] exploring the mechanisms and physiological basis of healing with LooH therapies (biological markers), with longer follow-ups, and determining an optimal dosage of LooH (frequency and duration).

5 | CONCLUSION

The present results suggest that kinesiotherapy, in combination with LooH with a spiritual component, was more effective for reducing knee pain and improving functioning than kinesiotherapy in combination with LooH without a spiritual component in older women with KOA; and more effective for reducing knee pain and improving functioning and QoL compared to kinesiotherapy alone. The mechanisms underlying the effect of CAM therapies in OA should be further explored in future studies.

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None

CONFLICT OF INTEREST

The authors declare no competing interests.

ETHICAL APPROVAL

This study was approved by the Research Ethics Committee of the Federal University of Juiz de Fora, Brazil under registry CAAE 52 623 115.0.0000.5147.

CONSENT TO PARTICIPATE

All participants signed a consent term.

DATA AVAILABILITY STATEMENT

Data are available upon request to the corresponding author.

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REFERENCES

1. Yu D, Jordan KP, Bedson J, et al. Population trends in the incidence and initial management of osteoarthritis: age- period- cohort analysis of the Clinical Practice Research Datalink, 1992–2013. *Rheumatology*. 2017;56(11):1902-1917.
2. Wesseling J, Welsing PMJ, Bierma-Zeinstra SMA, et al. Impact of self- reported comorbidity on physical and mental health status in early symptomatic osteoarthritis: the CHECK (Cohort Hip and Cohort Knee) study. *Rheumatology*. 2013;52(1):180-188.
3. Creamer P, Lethbridge-Cejku M, Costa P, Tobin JD, Herbst JH, Hochberg MC. The relationship of anxiety and depression with self-reported knee pain in the community: Data from the Baltimore longitudinal study of aging. *Arthritis Care Res (Hoboken)*. 2014;12(1):3-7.
4. McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage*. 2014;22(3):363-388.
5. Fernandes L, Hagen KB, Bijlsma JWJ, et al. EULAR recommendations for the non-pharmacological core management of hip and knee osteoarthritis. *Ann Rheum Dis*. 2013;72(7):1125-1135.
6. NICE. Osteoarthritis: care and management. Clinical guideline https://www.nice.org.uk/guidance/cg177: National Institute for Health and Clinical Excellence; 2014 [cited 2018 Feb, 13th]
7. Hochberg MC, Altman RD, April KT, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. *Arthritis Care Res*. 2012;64(4):465-474.
8. Papandony MC, Chou L, Seneviwickrama M, et al. Patients' perceived health service needs for osteoarthritis (OA) care: a scoping systematic review. *Osteoarthritis Cartilage*. 2017;25(7):1010-1025.
9. U.S. Department of Health & Human Services NIoH, National Center for Complementary and Integrative Health. Are You Considering a Complementary Health approach? https://nccih.nih.gov/sites/nccam.nih.gov/files/Are_You_Considering_08-11-2015.pdf2006 [updated 2014; cited 2018 Dec, 27th]
10. Tabatabaee A, Tafreshi MZ, Rassouli M, Aledavood SA, AlaviMajd H, Farahmand SK. Effect of therapeutic touch in patients with cancer: a literature review. *Medical archives (Sarajevo, Bosnia and Herzegovina)*. 2016;70(2):142-147.
11. Levin J. Energy healers: who they are and what they do. *Explore (NY)*. 2011;7(1):13-26.
12. Meehan TC. Therapeutic touch as a nursing intervention. *J Adv Nurs*. 1998;28(1):117-125.
13. Chen KW, Perlman A, Liao JG, Lam A, Staller J, Sigal LH. Effects of external qigong therapy on osteoarthritis of the knee. A randomized controlled trial. *Clin Rheumatol*. 2008;27(12):1497-1505.
14. Lu D-F, Hart LK, Lutgendorf SK, Perkhounkova Y. The effect of healing touch on the pain and mobility of persons with osteoarthritis: A feasibility study. *Geriatric Nursing*. 2013;34(4):314-322.
15. Gordon A, Merenstein JH, D'Amico F, Hudgens D. The effects of therapeutic touch on patients with osteoarthritis of the knee. *J Fam Pract*. 1998;47(4):271-277.
16. Peck SD. The efficacy of therapeutic touch for improving functional ability in elders with degenerative arthritis. *Nursing Science Quarterly*. 1998;11(3):123-133.
17. Smith AA, Kimmel SR, Milz SA. Effects of therapeutic touch on pain, function and well being in persons with osteo-arthritis of the knee: a pilot study. *Int J Advan Nurs Pract*. 2009;10(2):1-19.
18. IBGE. Censo Demográfico 2010: Características gerais da população, religião e pessoas com deficiência. Rio de Janeiro: Ministério do Planejamento, Orçamento e Gestão / Instituto Brasileiro de Geografia e Estatística – IBGE 2010. 215 p.
19. Xavier FC. *In the realms of mediumship*. US: Edicei of America; 2011.
20. Lucchetti AL, Lucchetti G, Leão FC, Peres MF, Vallada H. Mental and Physical Health and Spiritual Healing: An Evaluation of Complementary Religious Therapies Provided by Spiritist Centers in the City of São Paulo, Brazil. *Cult Med Psychiatry*. 2016;40(3):404-421.
21. Lucchetti G, de Oliveira RF, Gonçalves JPdB, Ueda SMY, Mimica LMJ, Lucchetti ALG. Effect of Spiritist "passe" (Spiritual healing) on growth of bacterial cultures. *Complement Therapies Med*. 2013;21(6):627-632.
22. Carneiro EM, Moraes GV, Terra GA. Effectiveness of Spiritist Passe (Spiritual Healing) on the Psychophysiological Parameters in Hospitalized Patients. *Adv Mind Body Med*. 2016;30(3):4-10.
23. Carneiro EM, Barbosa LP, Marson JM, et al. Effectiveness of Spiritist "passe" (Spiritual healing) for anxiety levels, depression, pain, muscle tension, well-being, and physiological parameters in cardiovascular inpatients: a randomized controlled trial. *Complement Ther Med*. 2017;30:73-78.
24. Carneiro EM, Borges RMC, de Assis HMN, et al. Effect of Complementary Spiritist Therapy on emotional status, muscle tension, and wellbeing of inpatients with HIV/AIDS: a randomized controlled trial - single-blind. *J Complement Integr Med*. 2018;1-8.
25. Carneiro EM, Barbosa LP, Bittencourt ACS, et al. Effect of the spiritist "passe" (Spiritual Healing) on the hematological response and complications of hospitalized newborns: a randomized clinical trial. *Enferm Health Care*. 2018;7(1):30-40.
26. Carneiro EM, Barbosa LP, Bittencourt AC, et al. Effects of Spiritist "passe" (Spiritual healing) on stress hormone, pain, physiological parameters and length of stay in preterm newborns: a randomized, double-blind controlled trial. *J Complement Integr Med*. 2018;15(4):1-8.

27. Carneiro EM, Tosta AM, Antonelli IBS, et al. Effect of Spiritist "Passe" on Preoperative Anxiety of Surgical Patients: A Randomized Controlled Trial, Double-Blind. *J Relig Health*. 2019.
28. Zacaron KAM, da Silva MN, Cotta e Silva Y, Lucchetti G. 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. *J Integr Med*. 2018;16(2):106-112.
29. Kellgren JH, Lawrence JS. Radiological assessment of osteo-arthrosis. *Ann Rheum Dis*. 1957;16(4):494-502.
30. Fernandes MI, Ferraz MB, Ciconelli RM. Tradução e validação do questionário de qualidade de vida para osteoartrose (WOMAC) para língua portuguesa. *Rev Paulista Reum*. 2003;10:25.
31. Bertolucci PHF, Brucki SMD, Campacci SR, Juliano Y. The mini mental state examination in an outpatient population: influence of literacy. *Arq Neuropsiquiatr*. 1994;52(1):1-7.
32. Ozalevli S, Ucan ES. The comparison of different dyspnoea scales in patients with COPD. *J Eval Clin Pract*. 2006;12(5):532-538.
33. Lucchetti G, Granero Lucchetti AL, Peres MF, Leao FC, Moreira-Almeida A, Koenig HG. Validation of the Duke Religion Index: DUREL (Portuguese version). *J Relig Health*. 2012;51(2):579-586.
34. Lucchetti G, Lucchetti AL, de Bernardin Goncalves JP, Vallada HP. Validation of the Portuguese version of the Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being scale (FACIT-Sp 12) among Brazilian psychiatric inpatients. *J Relig Health*. 2015;54(1):112-121.
35. Marina B, Valentin B, Keli Silva L, Marcela Augusta T, Sandra SR. Validação transcultural do teste de orientação da vida (TOV-R). *Estudos de Psicologia*. 2002;7(2):251-258.
36. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. *J Behav Ther Exp Psychiatry*. 2000;31(2):73-86.
37. Bellamy N, Wilson C, Hendrikz J. Population-Based Normative Values for the Western Ontario and McMaster (WOMAC) Osteoarthritis Index: Part I. *Semin Arthritis Rheum*. 2011;41(2):139-148.
38. Botega NJ, Márcia RB, Maria Adriana Z, Celso G Jr, Walter ABP. Mood disorders among medical in-patients: a validation study of the hospital anxiety and depression scale (HAD). *Revista de Saúde Pública*. 1995;29(5):359-363.
39. Bohannon RW. Reference values for the timed up and go test: a descriptive meta-analysis. *J Geriatr Phys Ther*. 2006;29(2):64-68.
40. Rocha NS, Fleck MP. Validity of the Brazilian version of WHOQOL-BREF in depressed patients using Rasch modelling. *Rev Saude Publica*. 2009;43(1):147-153.
41. Holmgren T, Hallgren HB, Öberg B, Adolfsson L, Johansson K. Effect of specific exercise strategy on need for surgery in patients with subacromial impingement syndrome: randomised controlled study. *Br J Sports Med*. 2014;48(19):1456-1457.
42. Albuquerque AS, Tróccoli BT. Development of a subjective well-being scale. *Psicologia: Teoria e Pesquisa*. 2004;20(2):153-164.
43. Collins NJ, Misra D, Felson DT, Crossley KM, Roos EM. Measures of knee function: International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form, Knee Injury and Osteoarthritis Outcome Score (KOOS), Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form (KOOS-PS), Knee Outcome Survey Activities of Daily Living Scale (KOS-ADL), Lysholm Knee Scoring Scale, Oxford Knee Score (OKS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Activity Rating Scale (ARS), and Tegner Activity Score (TAS). *Arthritis Care Res (Hoboken)*. 2011;63(Suppl 11):S208-S228.
44. Chen K, He B, Rihacek G, Sigal LH. A pilot trial of external Qigong therapy for arthritis. *J Clin Rheumatol*. 2003;9(5):332-335.
45. de Souza CR, Banin VB, de Moura Ribeiro Paula NA,, et al. Effect of the Spiritist "passe" energy therapy in reducing anxiety in volunteers: a randomized controlled trial. *Complement Ther Med*. 2016;27:18-24.
46. Angst F, Aeschlimann A, Stucki G. Smallest detectable and minimal clinically important differences of rehabilitation intervention with their implications for required sample sizes using WOMAC and SF-36 quality of life measurement instruments in patients with osteoarthritis of the lower extremities. *Arthritis Rheum*. 2001;45(4):384-391.
47. Kelly AM. The minimum clinically significant difference in visual analogue scale pain score does not differ with severity of pain. *Emerg Med J*. 2001;18(3):205-207.
48. Roe CA, Sonnex C, Roxburgh EC. Two meta-analyses of noncontact healing studies. *Explore*. 2015;11(1):11-23.
49. Dobson F, Hinman RS, Roos EM, et al. OARSI recommended performance-based tests to assess physical function in people diagnosed with hip or knee osteoarthritis. *Osteoarthritis Cartilage*. 2013;21(8):1042-1052.
50. French HP, Fitzpatrick M, FitzGerald O. Responsiveness of physical function outcomes following physiotherapy intervention for osteoarthritis of the knee: an outcome comparison study. *Physiotherapy*. 2011;97(4):302-308.
51. Hart J. Healing touch, therapeutic touch, and Reiki: Energy medicine advances in the medical community. *Alternat Complement Therap*. 2012;18(6):309-313.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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