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Physiotherapy and a Homeopathic Complex for Chronic Low Back Pain Due to Osteoarthritis: A Randomized, Controlled Pilot Study

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ABSTRACT

Context: Osteoarthritis (OA) is a common cause of chronic low back pain (CLBP) and can be managed with the use of drug therapy and physiotherapy. Homeopathic remedies may assist in the management of OA; however, research that supports their effectiveness is limited.

Objectives: The study aimed to investigate the efficacy of a homeopathic complex in combination with physiotherapy in the treatment of CLBP due to OA.

Design: The study was a six-week, randomized, double-blind, placebo-controlled pilot.

Setting: The study took place in a private physiotherapy practice in Gauteng, South Africa.

Participants: The participants were 30 males and females, aged 45-75 years, who were receiving physiotherapy treatment for OA of the lumbar spine from a therapist in private practice.

Interventions: The intervention and control groups both received standard physiotherapy treatment—massage, thermal therapy, and joint mobilization—every 2 weeks. In addition, the treatment group received a homeopathic complex—6cH each of *Arnica montana, Bryonia alba, Causticum, Kalmia latifolia, Rhus toxicodendron,* and *Calcarea fluorica*. The control group a received a placebo.

Outcome measures: The primary measure was a visual analogue scale (VAS) for pain. Secondary outcome measures included the Oswestry Disability Index (ODI), an evaluation of each patient's range of motion (ROM) of the lumbar spine, and a determination of each patient's need for pain medication.

Results: Intergroup analysis revealed that the treatment group significantly outperformed the control group with regard to pain, daily functioning, and ROM. No difference existed between the groups, however, in the need for conventional pain medication.
Conclusions: The study was too small to be conclusive, but results suggest that the homeopathic complex, together with physiotherapy, can improve symptoms associated with chronic low back pain due to OA significantly.

Keywords: Physiotherapy, homeopathy, homeopathic complex, chronic low back pain, osteoarthritis

Osteoarthritis (OA) is the most common cause of disability in older adults and affects approximately 9.6% of men and 18% of women worldwide over the age of 60 years.[1] Chronic low back pain (CLBP) resulting from spinal OA has a significant impact on the quality of life of sufferers, with the majority requiring ongoing rehabilitation and pain management; that treatment in turn places a large burden on the healthcare system.[2-4]

Physiotherapy may play a beneficial role in the management of CLBP. Due to the diversity of treatments and the lack of randomized control trials (RCTs) on the effectiveness of the treatment modalities, however, it is normally used in conjunction with drug therapy.[5,6] While drug therapy shows evidence of short-term effectiveness for CLBP, it is unfortunately also associated with numerous adverse effects. Insufficient evidence is available to identify a medication that offers a clear, overall, net advantage because of the complex balance between benefits and harms.[7]

Studies have shown a proclivity among patients with arthritis to seek out complementary and alternative (CAM) treatments. Research indicates that 80%-90% of arthritis sufferers, in some instances, make use of some form of CAM for the treatment of their symptoms.[8-10]

Homeopathy is a complementary treatment modality that makes use of highly dilute remedies, usually from natural sources.[11] It has been proposed that homeopathic remedies restore homeostatic functioning by modulating the biological systems within the body rather than by exerting direct pharmacological effects.[12] Homeopathic medicines are prepared through a process of sequential dilution and succussion (vigorous shaking). Centesimal potencies (c) are diluted in a 1:100 ratio, and use of the term *6cH* implies that the centesimal remedy has undergone serial dilution six times at 1:100.[13]

Limited evidence exists regarding the efficacy of homeopathic remedies for back pain. With regard to CLBP, a multicenter observational study has shown that individualized homeopathic treatment can improve quality of life and provided symptomatic relief to sufferers.[14] One RCT showed the efficacy of a homeopathic complex in the treatment of CLBP,[15] while another randomized, partly double-blind trial on the efficacy of the combination of 2 injectable homeopathic complexes found that they were not superior to a placebo.[16] A double-blind comparative study investigated the efficacy of a topical homeopathic complex in the treatment of acute low back pain and found it to be safer than and as effective as a capsicum-based product.[17] Homeopathy may potentially offer an alternative to drug therapy for CLBP patients who are undergoing physiotherapy treatments; however, further investigation is needed.

METHODS

The study was a six-week, randomized, double-blind, placebo-controlled pilot. The aim of the study was to investigate the efficacy of a homoeopathic complex that was

combined with physiotherapy, the intervention group, in comparison to that of physiotherapy combined with a placebo, the control group, in the treatment of CLBP due to OA.

Participants

The study took place at a private physiotherapy practice in Soshanguve, Gauteng, South Africa. Forty patients, both males and females, who were receiving physiotherapy treatment for OA of the lumbar spine at the physiotherapy practice, were recruited by means of purposive sampling via a poster advertisement that was placed in the physiotherapist's private practice. Patients were included if they: (1) were aged 45-75 years; (2) had had symptomatic CLBP due to OA for more than 3 months, as diagnosed by a healthcare practitioner; (3) experienced symptoms of OA, such as pain and decreased range of motion, as subjectively reported and by physical examination; and (4) were receiving physiotherapy treatment from the identified physiotherapist.

Participants were excluded according to the following criteria: (1) were receiving any form of therapy other than physiotherapy; (2) had presented with acute LBP with the duration of 3 months or less; or (3) were suffering from CLBP as a result of disc herniation, compression fracture, lumbar spinal stenosis, or other spondylathropathy.

Individuals who responded to the poster advertisement were provided with an information form pertaining to the study, and after they had agreed to participate, were requested to sign a consent form. Participants attended an initial consultation where they underwent a physical-screening examination by a member of the research team.

The current study was given clearance by the Higher Degrees Committee (HDC05/02-10) and the Academic Ethics Committee (AEC05/02-10) of the Faculty of Health Sciences at the University of Johannesburg (UJ). Both committees report to the National Health Research Ethics Council in South Africa. All participants were assured of privacy, confidentiality, and anonymity, with the right to withdraw from the study at any time.

Procedures

Over the six-week period of the study, both the intervention and control groups received standard physiotherapy treatment from the identified physiotherapist. In addition, participants received either a placebo or the homeopathic complex. Consultations with the therapist occurred at baseline (week 0) and at the end of weeks 2, 4, and 6. During each consultation, participants completed the Oswestry Disability Index (ODI), received a lumbar-spine range of motion (ROM) test using an attraction-tape measurement, and underwent a physical examination in which they rated lumbar pain, both with and without palpation, using a visual analogue scale (VAS). Participants were also requested to record the amount of pain medication that they took over the study's period.

Participants meeting the inclusion criteria were randomly allocated to the intervention or the control group. The medication bottles used in the study, containing either a homeopathic remedy or a placebo, were numbered and randomized by an independent individual using a simple randomization method. Participants selected a pre-numbered bottle, thereby allocating themselves randomly to one of the groups.

The researcher and participants were blinded and were unaware of which bottles contained the complex or the placebo, ensuring allocation concealment and preventing selection bias.

Intervention

Physiotherapy treatment. All participants underwent a 30-minute session once every 2 weeks that consisted of lower-back classic massage, mobilization of lumbar joints, and the application of a heat pack.

Homeopathic complex and placebo. The treatment group received the homeopathic complex, and the control group received unmedicated lactose tablets that looked and tasted the same as the complex. Participants in both groups were instructed to take 2 tablets, dissolved under the tongue, 20 minutes before meals, twice daily for the study's six-week period. Overall each participant received 168 tablets; 56 tablets were issued fortnightly to assess each participant's compliance in taking his or her medicine.

The homoeopathic complex consisted of 6 remedies clinically indicated for the treatment of LBP. The tablet contained 6cH each of *Arnica montana, Bryonia alba, Causticum, Kalmia latifolia, Rhus toxicodendron,* and *Calcarea fluorica.* The remedies were manufactured by CoMed (Pretoria, Gauteng, South Africa), a homoeopathic laboratory that employs the good manufacturing procedures and quality control that forms the basis for quality assurance. The complex was compounded at UJ's homoeopathic clinic by a qualified dispenser.

Outcome Measures

A pain score that was determined using a visual analogue scale (VAS) was the primary outcome measure. The Oswestry Disability Index (ODI), a lumbar-spine range of motion (ROM) test, and a determination of the amount of pain medication needed were employed as secondary outcome measures.

VAS. The VAS for pain is an established and validated tool that is used in determining the subjective level of pain of an individual.[18] The VAS scale used in the current study consisted of an 11-point grading scale where 0=no pain and 10=worst pain.

ODI. The ODI is a valid tool for measuring a patient's functional disability and is considered the gold standard of tests of outcomes related to low back pain. Each section is rated on a six-point scale (0-5), with 0 representing no limitation and 5 representing a maximal limitation. The total maximum score is 50, which is doubled to create a score out of 100, which is then interpreted as a percentage of patient-perceived disability; ie, the higher the score, the greater the disability.[19]

ROM. ROM is routinely measured in patients with low back pain to determine the functional limits of the spine. The attraction-tape measurement is a standard approach that involves the use of a tape measure, placed directly over the lumbar spine while the patient bends as far as they can. A 0-cm mark is represented by the spinal intersection of a horizontal line drawn between the left and right posterior, superior iliac spines. From that point, a second mark is placed 10 cm superior to the first mark, the lumbar flexion reference, and a third mark is placed 5 cm inferior to the first mark, the lumbar extension reference. The method has demonstrated test reliability and can differentiate a patient with a normal spine from those with significantly limiting LBP.[20]

Statistical Analysis

In the context of the current, small pilot study, the research team felt that a total of 30 participants would be sufficient, because 30 was the minimum number of participants needed to ensure adequate statistical power to determine valid scientific effects.[21]

Data was processed statistically using SPSS software, version 18.0; SPSS (Carey, NC, USA). The Shapiro Wilk test was applied, which showed an abnormal distribution of data, and therefore, nonparametric tests were chosen for the analysis. The Friedman and Wilcoxon Signed Ranks Tests were used for intragroup analysis, and the Mann-Whitney U test and

Independent Samples t-test were used for intergroup analysis. For the purpose of the study, the p-values, at a 95% confidence interval, were interpreted as follows: $p<0.05$ was statistically significant. For the Wilcoxon Test, the Bonferroni adjustment was applied to correct for multiple comparisons, and therefore, $p<0.016$ was statistically significant.

RESULTS

Figure 1 shows the consort flow diagram; 40 volunteers were assessed for eligibility and 30 (75%) met the inclusion criteria. All 30 participants completed the study. Fifteen participants were in the control group, receiving physiotherapy + placebo, and 15 were in the treatment group, receiving physiotherapy + homeopathic complex. Table 1 displays the demographics and baseline characteristics of the participants. Both groups exhibited a similar age and gender distribution and mean values for pain and functional disability as well as ROM. The treatment group had a slightly higher use of pain medication compared to the control group.

>>Insert Figure 1<<

>>Insert Table 1<<

VAS Without Palpation

Intergroup analysis. No significant differences existed between the 2 groups at the first and second consultations, with $p=0.547$ and $p=0.516$, respectively. Significant differences, however, did occur in favor of the treatment group at the third and fourth consultations.

Intragroup analysis. The difference in median pain scores, over time, was 3 for the treatment group and 2 for the control group; therefore, the trend of improvement was greater for the treatment group (Figure 2). Both groups demonstrated a statistically significant improvement over time, from baseline to the end of the study, with the treatment group's results at $p<0.001$ [$\chi 2$ (3, n=15)=42.064] as opposed to the control group's at $p=0.002$ [$\chi 2$ (3, n=15) = 14.831]. Subsequent analysis indicated that the improvement occurred consistently over the study's period for both groups (Table 2).

>>Insert Figure 2<<

>>Insert Table 2<<

VAS With Palpation

Intergroup analysis. Statistically significant differences existed between groups in favor of the treatment group at each consultation: (1) week 0, $p=0.026$; (2) week 2, $p=0.002$; (3) week 4, $p<0.001$; and (4) week 6, $p<0.001$ ($U=32.500$, $z=-3.380$).

Intragroup analysis. The difference in median pain scores, over time, was 4 for the treatment group and only 2 for the control group (Figure 3). Both groups demonstrated a statistically significant improvement over time, from baseline to the end of the study (1) the treatment group, with $p<0.001$ [$\chi 2$ (3, n=15) = 41.596]; and (2) the control group, with $p<0.001$ [$\chi 2$ (3, n=5) = 23.974]. Subsequent analysis indicates that participants in the treatment group experienced significant pain relief consistently over the study's period whereas the control group showed significant improvement only at week 4 (Table 2).

>>Insert Figure 3<<

ODI

Intergroup analysis. No statistically significant differences existed between the 2 groups at the first and second consultations, with $p=0.835$ and $p=0.052$, respectively. A significant difference occurred, however, in the level of function between the groups in favor

of the treatment group at both the third and fourth consultations, with $p<0.001$ ($U=13.000$, $z=-4.144$) and $p<0.001$ ($U=10.000$, $z=-4.262$), respectively.

Intragroup analysis. Figure 4 shows that a reduction in the median values occurred for both the treatment (12%) and control (4%) groups, with statistically significant decreases in functional disability found over time: (1) the treatment group, with $p<0.001$ [$\chi 2$ (3, n=15) = 44.718] and (2) the control group, with $p<0.001$ [$\chi 2$ (3, n=15) = 33.622]. That improvement occurred consistently over the study's period as measured at each consultation (Table 2).

>>Insert Figure 4<<

ROM: Extension

Intergroup analysis. No statistically significant differences occurred between the 2 groups at the first, second, and third consultations, with $p=0.484$, $p=0.148$, $p=0.080$, respectively. However, a significant difference existed in favor of the treatment group at the fourth consultation, with $p=0.021$ ($U=61.500$, $z=-2.311$).

Intragroup analysis. The analysis showed that a statistically significant improvement in extension occurred over the study's period for the treatment group, which showed a 2-cm increase in the median, with $p<0.001$ [$\chi 2$ (3, n=15) = 34.964], but not for the control group, which showed a 1-cm increase in the median, with $p=0.051$ [$\chi 2$ (3, n=15) = 7.787] (Figure 5). Subsequent tests indicated that the improvement for the treatment group occurred consistently over each consultation (Table 2).

>>Insert Figure 5<<

ROM: Flexion

Intergroup analysis. No statistically significant differences existed between the 2 groups at the first and second consultations, with $p=0.899$ and $p= 0.200$, respectively. However, significant differences in flexion occurred in favor of the treatment group at the third and fourth consultations, with $p=0.041$ ($U=63.000$, $z=-2.122$) and $p=0.002$ ($U=39.500$, $z=-3.121$), respectively.

Intragroup analysis. A statistically significant improvement in flexion occurred over time, from baseline to the end of the study, for the treatment group, which showed a 2-cm increase in the median, with $p<0.001$ [$\chi 2$ (3, n=15) = 39.046], and for the control group, which showed a 1-cm increase in the median, with a $p=0.049$ [$\chi 2$ (3, n=15) = 7.838] (Figure 6). That improvement occurred consistently at each consultation for the treatment group but only from the fourth consultation for the control group (Table 2).

>>Insert Figure 6<<

Pain Medication

Intergroup analysis. No statistically significant differences were found between the 2 groups at week 0, with $p=0.53$; week 2, with $p=0.533$; week 4, with $p=0.934$; or week 6, with $p=0.531$), indicating that neither group outperformed the other.

Intragroup analysis. Participants in the treatment group initially took twice as much pain medication, at 40 tablets per week, than the control group, at 20 tablets per week. Participants in the control group recorded use of a fairly consistent quantity of pain medication during the study while the treatment group had a vast reduction in the amount of pain medication that they needed by week 6, at 10 tablets per week (Figure 7). That reduction was statistically significant for both the treatment group, with $p<0.001$ [$\chi 2$ (3, n=15) = 38.774], and the control group, with $p=0.007$ [$\chi 2$ (3, n=15) = 12.027]. For the treatment group, that improvement was evident within the first 2 weeks of the study, whereas for the control group, the change occurred only at week 4 (Table 2). The 2 groups were not initially matched for the variable; that fact could have had an impact on the results.

>>Insert Figure 7<<

DISCUSSION

The current pilot study aimed to investigate the efficacy of a homeopathic complex in combination with physiotherapy in comparison to physiotherapy alone in the treatment of CLBP due to OA. The results showed that participants in both the intervention group receiving physiotherapy and the homeopathic complex and the control group receiving physiotherapy and a placebo, had significant improvements over the six-week period in pain, functional ability, and range of motion as well as a consequent reduction in use of conventional pain medication. The treatment group, however, consistently showed greater improvements, and on average, outperformed the control group by the fourth week of the study. While physiotherapy alone provided benefits to OA patients with CLBP, the current study's results indicate that the addition of the homeopathic complex provided even greater symptom improvement.

Physiotherapy is often advocated for patients with CLBP as an initial form of conservative pain management and has been shown to provide significant short-term improvements in symptoms.[6,22] The physiotherapeutic techniques used in the current study included classical massage, joint mobilization, and thermal therapy.[23] While state that spinal manipulation provides moderately superior results over a control therapy in the treatment of LBP, classical massage and thermotherapy, when used on their own, do not demonstrate efficacy.[5] With regard to CLBP due to OA, physiotherapy is traditionally used in combination with drug therapy. Drugs such as paracetamol, acetaminophen, nonsteroidal anti-inflammatories (NSAIDs) and intra-articular corticosteroid injections are commonly prescribed.

Those drugs provide temporary palliation of symptoms but are unfortunately associated with numerous adverse effects, particularly NSAIDs, which are related to an increased incidence of gastrointestinal complications.[24,25] Some NSAIDs have been linked to increased risk of death and morbidity in patients with cardiovascular disease.[26] Participants in the current study were not asked to discontinue their conventional drugs; however, the frequency of use was recorded daily. The type of medication used, however, was not standardized, and that fact could have had an impact on the results.

Homeopathy is one of the most frequently sought out complementary modalities by patients with rheumatic diseases.[27] Homeopathy has a wide range of remedies that may be useful in the management of OA symptoms[28] and potentially provide an alternative treatment to drug therapy. A 12-month, observational, cohort study conducted in France found that patients with musculoskeletal disease who consulted homeopathic physicians tended to use fewer NSAIDs than those who used conventional medicine alone, thereby reducing NSAID-related adverse events.[29] In one study comparing the efficacy of homeopathy with standardized physiotherapy in the treatment of CLBP, the homeopathy group reported a significant improvement in daily functioning, and the treatment was generally well-tolerated.[30]

Homeopathic remedies are believed to stimulate physiological responses in the body without always being pharmacologically detectable themselves. Potentized remedies, therefore, appear to demonstrate no toxicity or addictive properties.[31] Also, due to their high amount of dilution, homeopathic remedies are considered unlikely to cause drug interactions.

High dilutions do not, however, equate to medicinal inactivity, and very high dilutions have demonstrated effects in humans, plants, animals, cell-cultures, and individual cells.[13,32-34] For example, one study that examined the modulating effect on induced arthritis in rats of *Rhus toxicodendron* in various potencies/dilutions from low to high, found that the remedy in all potencies showed anti-arthritic activity.[35]

The remedies chosen for the currently used complex are all clinically indicated for CLBP. The choice of potency in the current study, a 6cH, is considered a relatively low potency or dilution, which is recommended when treating a chronic, physical pathology[36]; however, investigation using other potencies is warranted.

No severe side effects were reported in the current study; however, 5 participants in the treatment group did report an incident of mild abdominal cramping and diarrhea on the first day of treatment that lasted for no longer than 24 hours. Thereafter, those participants reported an improvement of their CLBP pain. That side effect was an unexpected finding, and it did not occur in any of the control participants. The highly diluted nature of the remedies used in the current study precluded the issue being the result of toxicity. According to De Schepper,[36] after the commencement of homeopathic treatment, minor eliminations from the body such as diarrhea, followed by an improvement in the patient's existing symptoms, is evidence of the healing process and is part of the body's healing response known as Herings law of cure.[37] Adverse effects in homeopathic treatment, if they do occur, are typically mild and transient.[11]

Limitations of the study

An important limitation of the study resulted from and conducting the study from a single physiotherapy practice. Future research should look at conducting a broader study.

The most important limitations of the study were the small sample size and the short duration of the study. A longer treatment period would help assess whether or not the trend of improvement would continue over time.

CONCLUSIONS

The current randomized, double-blind, placebo-controlled pilot study aimed to determine the efficacy of the combination of homeopathy and physiotherapy in the treatment of CLBP due to OA. The primary outcome measure was a determination of changes in pain, as determined by a VAS. Results showed that the treatment group significantly outperformed the control group with regard to reductions in pain and improvements in daily functioning and range of motion. No statistically significant differences occurred, however, between the groups in the need for conventional pain medication. Based on those results, the 2 treatment modalities used in combination may provide symptomatic relief for OA sufferers with CLBP; however, further large-scale studies of longer duration are warranted to verify the findings.

Acknowledgements: The authors would like to thank Jurgen Becker for his assistance with the statistical analysis.

Authors' Disclosure Statement: The current study was financed and supported by the University of Johannesburg (UJ), clinical trial registration number: NCT02207998. The contents of the work are solely the responsibility of the authors and do not represent the official views of UJ. The authors have no conflicts of interest related to the study.

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