Individualised homoeopathic medicine versus placebo in the pain management of knee and hip osteoarthritis: A double-blind, randomised controlled trial

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Abstract
Background: Osteoarthritis (OA) is a progressive, degenerative disease affecting large weight-bearing joints. The severity of symptoms varies among individuals; whereas pain and stiffness are the most troublesome complaints. Homoeopathic medicines have the potential to manage pain episodes.
Objective: The aim of the study was to assess the effect of individualised homoeopathic medicine (IHM) in managing the pain of knee and hip OA.
Methods: A prospective, double-blind, randomised (1:1) placebo-controlled trial was conducted on 60 individuals suffering from OA at R.B.T.S. Govt. Homoeopathic Medical College and Hospital, Muzaffarpur. Visual analogue scale for pain (Score-A-1), stiffness (Score-A-2) and loss of function (Score-A-3) was the primary outcomes and the OKHQOL scale (Score-B) was the secondary outcome. The outcomes were measured at baseline and after 3 months. Comparative analysis was done to detect group differences. Intra and intergroup analysis was done by paired and unpaired t-tests, respectively.
Results: Statistically significant results were observed in both intra and intergroup outcomes (P < 0.05, at 95% CI). The group differences in Score-A-1 (mean difference: −5.83, 95% CI: −6.71 to −4.94, P < 0.001), Score-A-2 (mean difference: −5.43, 95% CI: −6.38 to −4.48, P < 0.001), Score-A-3 (mean difference: −5.60, 95% CI: −6.50 to −4.69, P < 0.001) and in Score-B (mean difference: −106.87, 95% CI: −142.77 to −70.96, P < 0.001) were statistically significant after 3 months. However, the improvement was much better in the IHM group than in the placebo group. The frequently indicated medicines were Rhus toxicodendron, Medorrhinum, Bryonia and Syphilinum.
Conclusion: This study shows that IHMs can improve the pain in knee and hip OA, as well as the quality of life.

Acknowledgments and Source of Funding
Acknowledgements: The authors acknowledge Dr. S.N. Ojha, Principal, R.B.T.S. Government Homeopathic Medical College and Hospital, for allowing us to carry out the study successfully in this institution. The authors also remain grateful to the patients for their participation in the study.
Individualised homoeopathic medicine versus placebo in the pain management of knee and hip osteoarthritis: A double-blind, randomised controlled trial

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Abstract

Background: Osteoarthritis (OA) is a progressive, degenerative disease affecting large weight-bearing joints. The severity of symptoms varies among individuals; whereas pain and stiffness are the most troublesome complaints. Homoeopathic medicines have the potential to manage pain episodes. Objective: The aim of the study was to assess the effect of individualised homoeopathic medicine (IHM) in managing the pain of knee and hip OA. Methods: A prospective, double-blind, randomised (1:1) placebo-controlled trial was conducted on 60 individuals suffering from OA at R.B.T.S. Govt. Homoeopathic Medical College and Hospital, Muzaffarpur. Visual analogue scale for pain (Score-A-1), stiffness (Score-A-2) and loss of function (Score-A-3) was the primary outcomes and the OKHQOL scale (Score-B) was the secondary outcome. The outcomes were measured at baseline and after 3 months. Comparative analysis was done to detect group differences. Intra and intergroup analysis was done by paired and unpaired t-tests, respectively. Results: Statistically significant results were observed in both intra and intergroup outcomes (P<0.05, at 95% CI). The group differences in Score-A-1 (mean difference: −5.83, 95% CI: −6.71 to−4.94, P < 0.001), Score-A-2 (mean difference: −5.43, 95% CI: −6.38 to−4.48, P < 0.001), Score-A-3 (mean difference: −5.60, 95% CI: −6.50 to−4.69, P < 0.001) and in Score-B (mean difference: −106.87, 95% CI: −142.77 to−70.96, P < 0.001) were statistically significant after 3 months. However, the improvement was much better in the IHM group than in the placebo group. The frequently indicated medicines were Rhus toxicodendron, Medorrhinum, Bryonia and Sypilinum. Conclusion: This study shows that IHMs can improve the pain in knee and hip OA, as well as the quality of life.

Keywords: Hip, individualised homoeopathic medicine, knee, osteoarthritis knee and hip quality of life, osteoarthritis, visual analogue scale.

Introduction

Osteoarthritis (OA) is a chronic degenerative disorder characterised by the loss of articular cartilage, diminished joint space, hypertrophy of the margins of bone with subchondral sclerosis and biochemical and morphological changes of the synovial membrane and joint capsule.[1] Softening, ulceration and focal disintegration of the articular cartilage are pathological alterations in the late stage of OA. Synovial inflammation also may occur. Pain, particularly after prolonged activity and in the weight-bearing joints, is the common complaint, whereas stiffness is experienced after inactivity. It is probably not a single disease but represents the result of various disorders leading to joint failure. It is also known as degenerative arthritis, which commonly affects the hands, feet, spine and large weight-bearing joints, such as the hips and knees.[1,2] Clinical symptoms of OA are very significant for diagnosis. Clinical diagnosis is established using the standard American College Rheumatology guidelines.[3,4] Radiological imaging such as magnetic resonance imaging (MRI) and X-ray is helpful for the diagnosis of OA.[3] OA is the second most common rheumatologic problem and it is the most frequent joint disease with a prevalence of 22–39% in India.[3] OA is more common in women than in men, but the prevalence increases dramatically with age. Nearly 45% of women over the age of 65 years have symptoms, while radiological evidence confirms that 70% of OA cases are in
those over 65 years of age. OA of the knee is a major cause of mobility impairment, particularly among females. In most cases of OA, no apparent cause is identified, which is referred to as primary OA. Primary OA is mostly related to ageing. It can present as localised, generalised or erosive OA. Secondary OA is caused by another disease or condition. However, based on pathogenesis, OA has two clinical forms: Primary OA which occurs in the elderly, more common in females and secondary OA which can occur at any age due to previous wear or injury.

The cervical and lumbosacral spine, hip, knee, and first metatarsal joints are frequently impacted. Many persons with X-ray evidence of OA have no joint symptoms, while the prevalence of structural abnormalities is important for understanding the disease pathophysiology. On the other hand, the prevalence of symptomatic OA is more important from the clinical and public health perspectives. The two major joints affected are the knee and hip where severe impairment occurs. Knee OA is more prevalent than hip OA.

The response of the treatment in OA can be evaluated by different scales, such as the visual analogue scale (VAS) or osteoarthritis knee and hip quality of life (OKHQOL) scale etc. The pain of OA temporarily gets relieved with conventional medical treatment, but may, in turn, cause headaches, rashes and gastrointestinal and cardiovascular problems. As a result, many patients are turning towards alternative therapies. The rheumatic problem is the most common problem encountered by alternative medicine practitioners. However, scientific research has so far not provided enough conclusive evidence for the effectiveness of alternative medicines for managing rheumatic problems.

In a double-blind, randomised and placebo-controlled study of 60 patients, a statistically significant reduction of pain, stiffness and loss of function VAS scores and osteoarthritis research society international scores was found with individualised homoeopathic medicine (IHM). However, in their study, the group differences were non-significant on every occasion and concluded that homoeopathy was not superior to placebo in managing pain of knee OA.

Keeping in view the necessity and the high prevalence of rheumatic conditions such as OA and paucity of robust scientific evidence on homoeopathic management of OA pain, the present study was conducted. Hence, the aim of the present study was to evaluate the effectiveness of IHMs in managing pain of knee and hip OA.

**Materials and Methods**

**Study design and settings**

The study was a prospective, double-blind, randomised, placebo-controlled and parallel-arm clinical trial conducted in the outpatient department (OPD) and inpatient department (IPD) of R.B.T.S Government Homoeopathic Medical College and Hospital, Muzaffarpur, India, from May 2021 to February 2022.

**Participants**

The patients who attended the OPD/IPD of R.B.T.S Government Homoeopathic Medical College and Hospital, Muzaffarpur, of either sexes, any religion, literate or illiterate, residing in and around areas of the study site and suffering from OA were screened for the following criteria for inclusion: Age 35–80 years, either sex, any socioeconomic strata, self-reported or pre-diagnosed cases of OA or clinically diagnosed as OA as per American College of Rheumatology criteria and willing to participate in the study were included in the study.

Patients with known cases of systemic diseases, psychiatric illness or other uncontrolled or life-threatening illnesses affecting the quality of life or any organ failure, congenital deformity (example: Genu varum, genu valgum, etc.) of physical disability or severe joint degeneration with marked joint narrowing, pregnant and lactating females or those with substance abuse and/or dependence, self-reported immune-compromised state, undergoing homoeopathic treatment for any chronic disease within the last 6 months and who did not give consent for participation were excluded from the study.

**Sample size estimation**

We planned to achieve a target sample of 60 patients (30 in each group) within the stipulated time (α=0.05 and power 80%). Taking into account the maximum of 20% dropouts, the total sample size was computed to be 72. A formal sample size calculation could not be done.

**Randomisation and allocation**

Intervention or control was implemented as per the random number chart created using the random number generator software StatTrek. The chart was generated using six blocks of size restricted to 10 (6 × 10 = 60) plus another block of size 6 to maintain alike allocation between groups and a 1:1 ratio easily; thus, the same number of patients was randomised to either code 1 or 2, either to intervention or control.

**Blinding**

The double blinding method was adopted. The patients and investigators were blinded throughout the study and were not involved in random-number generation, code allocation and dispensing of placebo/medicine to the patients. One of the study investigators, who were in charge of giving patients their medicine or placebo in accordance with the random number list, was given access to the randomisation chart. The pharmacist was also kept blinded throughout the study. Both medicine and placebo were packed in identical glass bottles and labelled with code, name of medicine and potency and were dispensed according to the random number list. Unblinding or disclosing of the randomisation codes was done after the study had been completed.
Intervention

**IHM (experimental group)**

Intervention was the indicated IHM in centesimal potencies, selected in each case based on the totality of symptoms according to homoeopathic principles. Appropriate repetition was done at suitable intervals as per the requirement of the case. Each dose consisted of 4–6 globules (No.30) medicated with a single drop of the indicated homoeopathic dilution. Each dose was directed to be taken orally on a clean tongue with an empty stomach. Medicines were obtained from the college pharmacy, which was procured from a GMP-certified pharmaceutical company that is, SBL Pvt. Ltd. In subsequent visits, the medicines and their potencies or doses and repetition were done in compliance with the homoeopathic principles.

**Placebo (control group)**

After a detailed case recording, the patients allocated to the control group were given a placebo, a non-medicinal substance but identical in appearance to the IHM group, for a period of 3 months. Each dose consisted of 4–6 sugar globules (No. 30) moistened with non-medicinal rectified spirit, to be taken orally on a clean tongue with an empty stomach.

**Study procedure**

The study was conducted on the patients from May 2021 to February 2022, after obtaining approval from the Institutional Ethical Committee of the hospital. A random selection of 72 cases of knee and hip OA was screened for the study, as per the inclusion and exclusion criteria. The enrolled participants were randomised either to the IHM or placebo group and their baseline data were recorded using a random number generator at StatTrek and block randomisation. A detailed case-taking of each participant was done, the symptoms were evaluated and the totality of symptoms was framed in accordance with the directions laid down by Dr. C. F. S. Hahnemann in the *Organon of Medicine*. The homoeopathic medicine was finally selected based on the instructions in the Organon of Medicine, in consultation with RADAR software and Homoeopathic Materia-Medica, as and when required. Each individual patient was followed up regularly for 3 months.

**Outcome assessment**

The response and improvement of the patients were observed in terms of primary and secondary outcomes.

**Primary outcomes**

VAS for pain, stiffness and limitation of physical function: The scores were based on self-reported measures of symptoms recorded with a single handwritten mark placed at 1 point, along the length of a 10-cm line that represented a continuum between the two ends of the scale ranging from ‘no pain’ on the left end (0 cm) of the scale to the ‘worst pain’ on the right end of the scale (10 cm).

**Secondary outcome**

OKHQOL scale is a 10-point Likert scale ranging from ‘not at all’ to ‘a great deal’ about the alterations in the quality of life brought about by knee and hip OA.

All the outcome measures were assessed at baseline (0 months) and 3 months, respectively. A specially designed Microsoft MS Office Excel 2007 spreadsheet (master chart) was used for data extraction.

**Statistical techniques and data analysis**

The analysis was done for the effect of individualised homoeopathic and placebo treatment on knee and hip OA cases with the help of standard statistical methods. The baseline data (categorical and continuous) were presented in terms of absolute values, percentages (%), mean ± standard deviation (SD) etc., as appropriate. Paired t-test was used to analyse the intragroup changes that occurred in the values of VAS and OKHQOL scores before and after treatment as a result of the intervention. The intergroup differences were tested using ‘Unpaired t-test’ at the end of the study (3 months). \( P < 0.05 \) (2-tailed) at 95% C.I was considered to be statistically significant. The statistical calculations were done using SPSS®-IBM® software version 22.

The present study is being reported as per the Consolidated Standards of Reporting Trials (CONSORT) for randomised trials and the RedHot guidelines for reporting data on homoeopathic treatment.

**Ethical statements**

The study protocol was approved by the Institutional Ethical Committee (IEC) of R.B.T.S Govt. Homoeopathic Medical College and Hospital (vide Ref. No.- RBTS/ETHICS-22, Dated: 23 June 2020) and thereafter registered prospectively in Clinical Trials Registry – India (CTRI) before enrolling the patients in the study (CTRI/2021/04/032788, Dated – 30 April 2021. Each patient was informed of the ethical issues related to the study through the informed consent form which was duly documented. The patients were instructed to report adverse events, either directly or over the phone. The study protocol conformed to the guidelines in the Declaration of Helsinki on human experimentation and good clinical practice (GCP) in India.

**RESULTS**

Between May 2021 and February 2022, 72 patients of Knee and Hip OA (OA knee \( n = 39 \); OA hip \( n = 22 \); both \( n = 11 \)) were screened for 2 months as per the pre-specified inclusion and exclusion criteria. Out of these 72 screened cases (OA knee: \( n = 39 \); OA hip: \( n = 22 \); both: \( n = 11 \)), six were excluded due to various reasons as reflected in the study flow diagram [Figure 1]. A total of 66 patients met the eligibility criteria and were enrolled into either placebo or IHM group over a period of one month and followed-up for a period of 3 months. During treatment, six patients dropped out and 60 completed the trial (OA knee \( n = 36 \); OA hip \( n = 18 \); both \( n = 6 \)) [Figure 1]. Finally, 60 patients, 30 in the IHM group and 30 in the Placebo group, were considered for outcome analysis. Baseline demographics as illustrated in [Table 1] were similar for both the groups (\( P > 0.05 \), 2-tailed).
Baseline data
The distribution of sociodemographic features including age, sex, body mass index (BMI), socioeconomic status, physical activity, family history and joints involved was similar between the IHM and placebo groups. No significant differences ($P > 0.05$, 2-tailed) existed between the two groups, as determined by unpaired $t$-tests and Chi-squared tests for continuous and categorical variables, respectively; thus, ensuring comparability of the two groups ($P > 0.05$, 2-tailed). The distribution of outcome measures at baseline was also comparable ($P > 0.05$, 2-tailed) except in score-A-2 ($t = 2.714$, $P = 0.009$, 2-tailed) and Score-B ($t = 2.446$, $P = 0.017$, 2-tailed) [Table 1].

For intra-group comparison, paired-$t$ tests were used, while unpaired-$t$ tests were used for inter-group comparison. Improvements in primary and secondary outcomes were higher in the IHM group, as compared to the placebo group.

Primary outcomes
Visual analogue scale for pain (score ‘A-1’)
Intragroup differences were analysed by paired-$t$-test at baseline and after 3 months and a statistically significant improvement was seen in the IHM group. The mean changed from $7.80 \pm 0.85$ to $2.57 \pm 2.32$ ($t = 11.27$, $P < 0.001$, 2-tailed) in the IHM group and from $8.07 \pm 0.91$ to $8.40 \pm 0.72$ in the placebo group ($t = -2.07$, $P = 0.05$, 2 tailed, statistically not significant) [Tables 2 and 3]. Unpaired $t$-test was used to analyse the group differences after 3 months of treatment. In contrast to the placebo group, the IHM group showed a marked reduction in scores. The group differences were statistically significant (mean difference: $-5.83$, 95% CI: $-6.71$ to $-4.94$, $t = -13.17$, $df = 58$, $P < 0.001$, 2 tailed) after 3 months of treatment [Table 4].

Visual analogue scale for stiffness (score ‘A-2’)
Intragroup reductions of scores in both IHM ($P < 0.001$, 2-tailed) and placebo ($P = 0.013$, 2-tailed) groups were statistically significant. The mean reduction was from $7.93 \pm 0.74$ to $2.33 \pm 2.35$ ($t = 12.41$, $df = 29$) in the IHM group and from $7.33 \pm 0.96$ to $7.76 \pm 1.10$ ($t = -2.64$, $df = 29$) in the placebo group. The group differences in VAS stiffness scores favoured the IHM group over the placebo group and the outcome was statistically significant (mean difference: $-5.43$, 95% CI: $-6.38$ to $-4.48$, $t = -11.45$, $df = 58$, $P < 0.001$, 2 tailed) after 3 months of treatment [Table 4].

Visual analogue scale for loss of function (score ‘A-3’)
The intra-group reductions of scores in both IHM ($P < 0.0001$, 2-tailed) and placebo ($P = 0.004$, 2-tailed) groups were
Table 1: Comparison of demographic characteristics of IHM and placebo groups at baseline (n=60)

<table>
<thead>
<tr>
<th>Variables</th>
<th>IHM group (n=30)</th>
<th>Placebo group (n=30)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>12 (40%)</td>
<td>11 (36.7%)</td>
<td>0.791</td>
</tr>
<tr>
<td>Female</td>
<td>18 (60%)</td>
<td>19 (63.3%)</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>46.83±12.4</td>
<td>47.10±9.1</td>
<td>0.93</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>26.77±4.4</td>
<td>27.17±4.68</td>
<td>0.735</td>
</tr>
<tr>
<td>Socioeconomic status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor</td>
<td>8 (26.7%)</td>
<td>6 (20%)</td>
<td>0.81</td>
</tr>
<tr>
<td>Middle</td>
<td>13 (43.3%)</td>
<td>15 (50%)</td>
<td></td>
</tr>
<tr>
<td>Affluent</td>
<td>9 (30%)</td>
<td>9 (30%)</td>
<td></td>
</tr>
<tr>
<td>Physical activity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sedentary</td>
<td>11 (36.7%)</td>
<td>10 (33.3%)</td>
<td>0.96</td>
</tr>
<tr>
<td>Light</td>
<td>7 (23.3%)</td>
<td>8 (26.7%)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>6 (20%)</td>
<td>7 (23.3%)</td>
<td></td>
</tr>
<tr>
<td>Heavy</td>
<td>6 (20%)</td>
<td>5 (16.7%)</td>
<td></td>
</tr>
<tr>
<td>Family history</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OA/rheumatism</td>
<td>7 (23.3%)</td>
<td>5 (16.7%)</td>
<td>0.52</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>23 (76.7%)</td>
<td>25 (83.3%)</td>
<td></td>
</tr>
<tr>
<td>Occupation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>House-wife</td>
<td>11 (36.67)</td>
<td>9 (30)</td>
<td>1.000</td>
</tr>
<tr>
<td>Teacher</td>
<td>5 (16.67)</td>
<td>6 (20%)</td>
<td></td>
</tr>
<tr>
<td>Employee</td>
<td>4 (13.33)</td>
<td>4 (13.33)</td>
<td></td>
</tr>
<tr>
<td>Business</td>
<td>3 (10%)</td>
<td>5 (16.67)</td>
<td></td>
</tr>
<tr>
<td>Worker</td>
<td>3 (10%)</td>
<td>2 (6.67)</td>
<td></td>
</tr>
<tr>
<td>Police officer</td>
<td>1 (3.33)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Auto-driver</td>
<td>2 (6.67)</td>
<td>2 (6.67)</td>
<td></td>
</tr>
<tr>
<td>Shop keeper</td>
<td>1 (3.33)</td>
<td>2 (6.67)</td>
<td></td>
</tr>
<tr>
<td>Joints involved</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knee</td>
<td>17 (56.7%)</td>
<td>17 (56.7%)</td>
<td>0.92</td>
</tr>
<tr>
<td>Hip</td>
<td>7 (23.3%)</td>
<td>8 (26.7%)</td>
<td></td>
</tr>
<tr>
<td>Both knee and hip</td>
<td>6 (20.0%)</td>
<td>5 (16.7%)</td>
<td></td>
</tr>
<tr>
<td>Baseline data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCORE ‘A-1’</td>
<td>7.80±0.8</td>
<td>8.07±0.9</td>
<td>0.24</td>
</tr>
<tr>
<td>SCORE ‘A-2’</td>
<td>7.93±0.7</td>
<td>7.33±1.0</td>
<td>0.009*</td>
</tr>
<tr>
<td>SCORE ‘A-3’</td>
<td>7.43±1.1</td>
<td>7.07±0.8</td>
<td>0.15</td>
</tr>
<tr>
<td>SCORE ‘B’</td>
<td>254.27±61.9</td>
<td>218.33±51.4</td>
<td>0.017*</td>
</tr>
</tbody>
</table>

SCORE ‘A-1’: VAS for pain; SCORE ‘A-2’: VAS for stiffness; SCORE ‘A-3’: VAS for loss of function; SCORE ‘B’: QoL; IHM: Individualised homoeopathic medicine. *Continuous data presented at mean±standard deviation and unpaired t-tests applied. **Categorical data presented as absolute values and percentage and Chi-square tests applied. *P<0.05 considered as statistically significant.

Table 2: Comparison of outcome measures in IHM group at baseline and after 3 months of treatment (n=30)

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Baseline (mean±SD)</th>
<th>After 3 months (mean±SD)</th>
<th>Mean difference</th>
<th>95% CI</th>
<th>t_{df}</th>
<th>P-value (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Outcome measures:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCORE ‘A-1’</td>
<td>7.80±0.85</td>
<td>2.57±2.32</td>
<td>5.23</td>
<td>4.28, 6.18</td>
<td>11.28</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>SCORE ‘A-2’</td>
<td>7.93±0.7</td>
<td>2.33±2.35</td>
<td>5.60</td>
<td>4.67, 6.52</td>
<td>12.41</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>SCORE ‘A-3’</td>
<td>7.43±1.14</td>
<td>2.07±2.21</td>
<td>5.37</td>
<td>4.38, 6.35</td>
<td>11.17</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Secondary outcome measures:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCORE ‘B’</td>
<td>254.27±61.8</td>
<td>113.73±83.80</td>
<td>140.53</td>
<td>112.63, 168.43</td>
<td>10.30</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

SCORE ‘A-1’: VAS for pain; SCORE ‘A-2’: VAS for stiffness; SCORE ‘A-3’: VAS for loss of function; SCORE ‘B’: QoL; SD: Standard deviation; df: Degree of freedom. t_{df}: t score at 29 degrees of freedom. IHM: Individualised homoeopathic medicine. *P value calculated by paired t-tests; P<0.05 considered statistically significant.

Statistically significant. The change of mean score in the IHM group was from 7.43 ± 1.14 to 2.07±2.21 (t = 11.17, df = 29) and in the placebo group from 7.06 ± 0.78 to 7.67 ± 1.09 (t = −3.16, df = 29) after 3 months of treatment [Tables 2 and 3]. The group differences in VAS for loss of function scores were also statistically significant in the IHM group (mean difference: −5.60, 95% CI: −6.50 to −4.69, t = −12.43, df = 58, P < 0.001, 2-tailed) a [Table 4].
**Secondary outcome**

**OKHQOL scale (Score ‘B’)**

Intra-group reductions of scores in both IHM (P < 0.001, 2-tailed) and placebo (P = 0.004, 2-tailed) groups were statistically significant. After 3 months of treatment, the mean changed in the IHM group from 254.27 ± 61.89 to 220.60 ± 51.29 (t = 10.30, df = 29) and in the placebo group from 218.33 ± 51.39 to 220.60 ± 51.39 (t = 2.07, df = 29) [Tables 2 and 3]. Group differences in OKHQOL scores are much in favour of the IHM group over the placebo group and the result was statistically significant (mean difference: −106.87, 95% CI: −142.77 to −70.96, t = −3.96, df = 58, P < 0.001, 2-tailed) after 3 months of treatment [Table 4].

**Frequently prescribed homoeopathic medicines**

Nine different medicines were prescribed at the baseline in the two groups [Table 5]. *Rhus toxicodendron* (n = 18; 30%), *Medorrhinum* (n = 14; 23.33%), *Bryonia alba* (n = 12; 20%) and *Syphilinum* (n = 6; 10%) were the most frequently prescribed medicines as shown in Figure 2. The common indications for prescribing these medicines are shown in Table 6. Most prescriptions were based on the specific pathological symptoms.

Homoeopathic intervention was found to be safe throughout the study period, as neither any death nor any serious adverse events were reported across the two groups. Two cases in the experimental group and one in the control group experienced mild illness; the cases in the medicinal group were treated with *Rhus toxicodendron* 30 cH and *Arsenicum album* 30 cH for common colds, while the case in the control group was treated with *Belladonna* 30 cH for tonsillitis.

**Discussion**

This double-blinded, randomised, placebo-controlled and clinical study highlights the role of homoeopathic medicines in the treatment of knee and hip OA. On thorough search, it was realised that there is a paucity of conclusive evidence-
Table 6: Indication of frequently prescribed homoeopathic medicines

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Frequently indicated medicine</th>
<th>Common indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td><em>Rhus toxicodendron</em></td>
<td>• Pain in the joint with stiffness&lt;in the morning, cold&gt;continued motion</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Restlessness and has to change their position frequently</td>
</tr>
<tr>
<td>2.</td>
<td><em>Syphilinum</em></td>
<td>• Pain in the joint&gt;at night, &gt;change of position, during daytime</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Pain increases and decreases gradually</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Falling of hair and excessive salivation</td>
</tr>
<tr>
<td>3.</td>
<td><em>Medorrhinum</em></td>
<td>• Pain, swelling with stiffness of the joint&gt;by motion, stretching, &gt; in damp weather</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Burning in hands and feet with fidgety of legs or feet</td>
</tr>
<tr>
<td>4.</td>
<td><em>Bryonia alba</em></td>
<td>• Pain in the joint&lt;from motion, &gt; rest</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Dryness of tongue with profuse thirst of cold water</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Constipation; stool- dry, hard</td>
</tr>
</tbody>
</table>

IHM: Individualised homoeopathic medicine

based studies on the use of IHM in OA in databases, such as PubMed, Google Scholar, Scopus, ScienceDirect and Web of Science. As a result, we planned to carry out this study. For assessing the response of the patients, two separate scoring systems were utilised. These were VAS (Score A) for pain, stiffness and limitation of physical function and the OKHQOL (Score B) scale. Statistically significant changes in various scores in the IHM group speak of the relevance of homoeopathy in the treatment of OA.

There are a limited number of studies that provide similar evidence. A study in the management of knee OA with homoeopathy in 100 patients was in favour of its role. *Bryonia alba, Rhus toxicodendron, Calcarea fluorica* and *Causticum* were the most indicated medicines.[25]

In another study, to evaluate the efficacy of *Rhus toxicodendron* in knee OA, positive results were obtained.[26] A single-blind, randomised and clinical study to assess the efficacy of homoeopathic medicines on OA showed statistically significant results in the IHM group. The frequently indicated medicines were *Bryonia alba, Medorrhinum, Pulsatilla pratensis, Rhus toxicodendron, Arnica Montana, Causticum* and *Sulphur*.[27]

Our study outcomes somewhat coincide with the findings of a previous study.[15] Where statistically significant reduction of pain, stiffness and loss of function VAS scores and OA Research Society International Scores were found in both Homoeopathy and Placebo groups. However, in their study, the group differences were not significant (*P* > 0.05) whereas in our present study, both inter and intragroup analyses have shown statistically significant improvement for both the scores (*P* < 0.05).

Being a double-blind, placebo-controlled, randomised and clinical trial, the outcome of this study will provide reliable evidence on the efficacy of IHM in the management of pain of knee and hip OA. One of the drawbacks of this study was that the sample size was relatively small. Moreover, since the outcome measures in this study were only subjective, it is more amenable to be influenced by the biases of the patients; the OKHQOL questionnaire was a lengthy one to be entertained by the patients.

To validate the findings, more randomised and controlled trials with larger samples should be conducted in the future, particularly focusing on the effect on the objective parameters, such as biochemical markers, ultrasonographic and MRI, as well as the subjective symptoms.

Further, apart from the centesimal potencies, degenerative diseases like OA can also be thought of being treated with LM potency[28] to alleviate the acute pain and to ensure a longstanding beneficial effect in a progressing pathology like OA. Since OA is progressive in nature, it should be addressed at the earliest to preserve unimpaired mobility of the affected part/joint. This intervention provided by homoeopathic constitutional aid could facilitate a complete relief of the symptomatology associated with OA, without any major adverse events. Further clinical trials are required to substantiate the findings of this work.
CONCLUSION
In this randomised and placebo-controlled study, IHMs have shown beneficial effects in managing the pain of Knee and Hip OA and also in improving the quality of life.

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None.

Conflicts of interest
There were no conflicts of interest.

REFERENCES
Individualised homöopathische Medizin versus Placebo bei der Schmerzbehandlung von Knie- und Hüftarthrose: Eine doppelblinde, randomisierte, kontrollierte Studie


Methoden: Eine prospektive, doppelblinde, randomisierte Studie wurde an 60 Personen mit Osteoarthritis am R.B.T.S. Govt. Homoeopathic Medical College and Hospital, Muzaffarpur, durchgeführt. VAS für Schmerzen (Score-A-1), Steifheit (Score-A-2) und Funktionsverlust (Score-A-3) waren die primären klinischen Endpunkte. Die sekundären Endpunkte waren die primären Endpunkte im Score-B (VAS, Steifheit, Funktionsverlust). Die Ergebnisse wurden mittels gepaarter t-Tests analysiert. Die Gruppenunterschiede in Score-A-1 (mittlere Differenz: -5,83, 95 % IC -6,71 bis -4,94, p<0,001), Score-A-2 (mittlere Differenz: -6,49, p=0,001) und Score-A-3 (mittlere Differenz: -6,9, p<0,001) waren nach 3 Monaten statistisch signifikant. Allerdings war die Verbesserung in der IHM-Gruppe wesentlich besser als in der Placebo-Gruppe. Die am häufigsten angegebenen Arzneimittel waren Rhus toxicodendron, Medorrhinum, Bryonia und Syphilinum

Schlussfolgerung: Diese Studie zeigt, dass individualisierte homöopathische Arzneimittel die Schmerzen bei Knie- und Hüftarthrose sowie die Lebensqualität verbessern können.
Khadim, et al.: Homoeopathic medicines in the management of pain of knee and hip osteoarthritis

Background: Osteoarthritis is a degenerative and progressive disease affecting large weight-bearing joints. The severity of symptoms varies from one person to another, but pain and stiffness are the most frequent complaints. Homoeopathic medicines can treat episodes of pain.

Objective: To evaluate the effect of individualized homoeopathic medicines in the management of pain of knee and hip osteoarthritis.

Methods: The study was a prospective, double-blind, randomized (1:1) and placebo-controlled trial conducted on 60 patients with osteoarthritis at the R.B.T.S. Government Homeopathic Medical College and Hospital in Muzaffarpur. The primary outcomes were pain (score A-1), stiffness (score A-2), and loss of function (score A-3), and the secondary outcome was the OKHQOL scale (score B). The results were measured at the start of the study and after 3 months. A comparative analysis was performed to detect differences between groups. Within-group and between-group analyses were conducted using paired and non-paired t-tests, respectively.

Results: Statistically significant results were observed both within and between groups (p<0.05, 95% CI). The differences between groups in the A-1 score (mean difference: -5.83, 95% CI: -6.71 to -4.94), A-2 score (mean difference: -5.43, 95% CI: -6.38 to -4.48), A-3 score (mean difference: -5.60, 95% CI: -6.50 to -4.69) and B score (mean difference: -106.87, 95% CI: -142.77 to -70.96) were statistically significant after 3 months. However, the improvement was much better in the IHM group compared to the placebo group.

Conclusions: This study demonstrates that individualized homoeopathic medicines can improve pain in knee and hip osteoarthritis, thereby improving quality of life.