Original Article

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: −6.71to−4.94, $P < 0.001$), Score-A-2 (mean difference: −5.43, 95% CI: −6.38to−4.48, $P < 0.001$), Score-A-3 (mean difference: −5.60, 95% CI: −6.50to-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.

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.[5] OA is the second most common rheumatologic problem and it is the most frequent joint disease with a prevalence of 22–39% in India.[1] 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

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those over 65 years of age. OA of the knee is a major cause of mobility impairment, particularly among females.[2,6] OA was estimated to be the tenth leading cause of nonfatal burden.[1]

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.[5]

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.[2,7]

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.[8,9]

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.[10,11] The rheumatic problem is the most common problem encountered by alternative medicine practitioners.[12] However, scientific research has so far not provided enough conclusive evidence for the effectiveness of alternative medicines for managing rheumatic problems.[13,14]

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.[15]

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[3,4] 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 vulgum, 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 ($6 \times 10 = 60$) 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*.[16] 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.[16-19] 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).[8]

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.[9]

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.[20]

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.[21,22]

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/2021/04/033278), 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[23] on human experimentation and good clinical practice (GCP) in India.[24]

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).

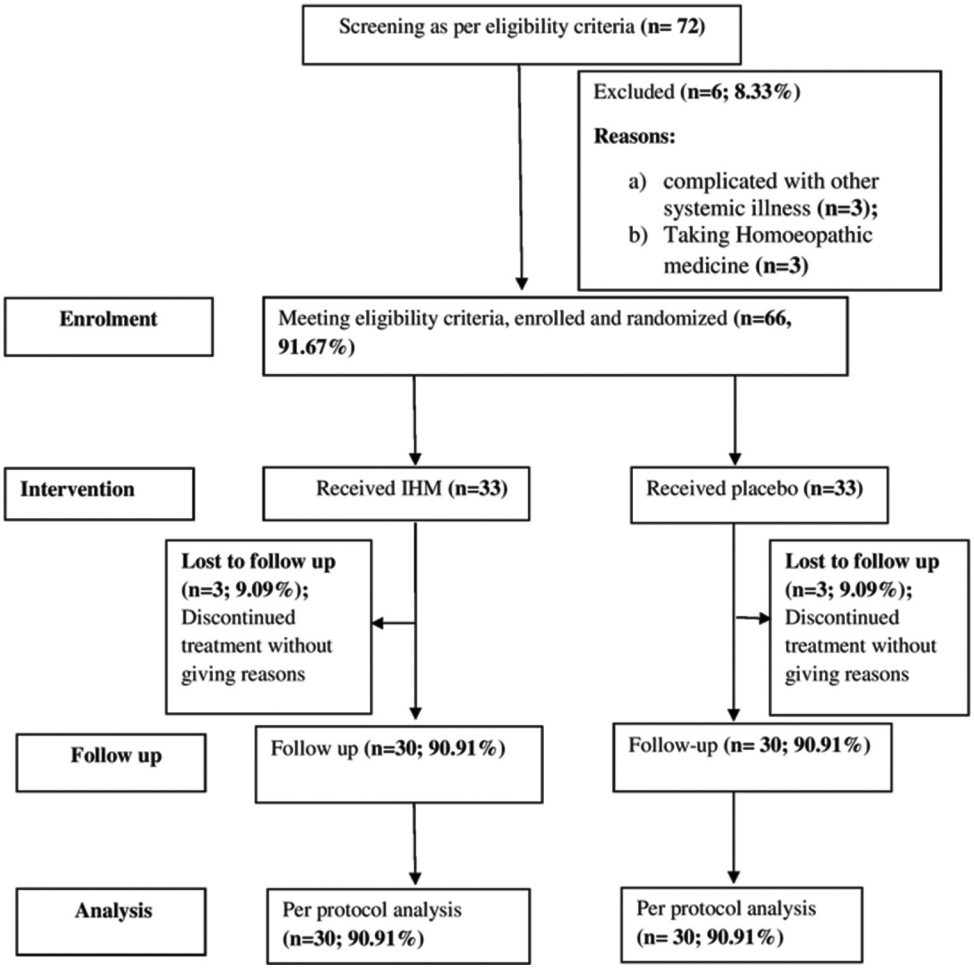

Figure 1: Study flow diagram

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 ± 0.85 to 2.57 ± 2.32 ($t = 11.27$, $P < 0.001$, 2-tailed) in the IHM group and from 8.07 ± 0.91 to 8.40 ± 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: to −6.71–−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 ± 0.74 to 2.33 ± 2.35 ($t = 12.41$, df = 29) in the IHM group and from 7.33 ± 0.96 to 7.76 ± 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)

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

SCORE 'A-1': VAS for pain; SCORE 'A-2': VAS for stiffness; SCORE 'A-3': VAS for loss of function; SCORE 'B': OAKQOL; IHM: Individualised homoeopathic medicine. [a]Continuous data presented at mean±standard deviation and unpaired *t*-tests applied. [b]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)

Outcomes	Baseline (mean±SD)	After 3 months (mean±SD)	Mean difference	95% CI	t_{29}	*P*-value (2-tailed)
Primary Outcome measures:						
SCORE 'A-1'	7.80±0.85	2.57±2.32	5.23	4.28, 6.18	11.28	<0.001*
SCORE 'A-2'	7.93±0.74	2.33±2.35	5.60	4.67, 6.52	12.41	<0.001*
SCORE 'A-3'	7.43±1.14	2.07±2.21	5.37	4.38, 6.35	11.17	<0.001*
Secondary outcome measures:						
SCORE 'B'	254.27±61.89	113.73±83.80	140.53	112.63, 168.43	10.30	<0.001*

SCORE 'A-1': VAS for Pain; SCORE 'A-2': VAS for Stiffness; SCORE 'A-3': VAS for Loss of Function; SCORE 'B': OAKQOL; SD: Standard deviation; df: Degree of freedom. t_{29}: 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 = −3.168, 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].

Table 3: Comparison of outcome measures of PLACEBO group at baseline and after treatment (*n*=30)

Outcomes	Before treatment (mean±SD)	After treatment (mean±SD)	Mean difference	95% CI	t_{29}	*P*-value
Primary Outcome measures:						
SCORE 'A-1'	8.07±0.91	8.40±0.72	−0.33	−0.67, −0.003	−2.07	0.05
SCORE 'A-2'	7.33±0.96	7.77±1.10	−0.43	−0.77, −0.09	−2.64	0.013*
SCORE 'A-3'	7.07±0.79	7.67±1.09	−0.60	−0.99, −0.21	−3.17	0.004*
Secondary outcome measures:						
SCORE 'B'	218.33±51.39	220.60±51.30	−2.27	−3.61, −0.92	-3.45	0.002*

SCORE 'A-1': VAS for Pain; SCORE 'A-2': VAS for Stiffness; SCORE 'A-3': VAS for Loss of Function; SCORE 'B': OAKQOL; SD: Standard deviation; df: Degree of Freedom. t_{29}: t score at 29 degrees of freedom. IHM: Individualised homoeopathic medicine. **P* value calculated by paired t-tests; $P<0.05$ considered statistically significant

Table 4: Comparison of outcome measures of IHM and PLACEBO group at the end of 3 months

Outcomes	Groups	Baseline Mean±SD	After 3 months Mean±SD	Mean difference±SE	95% CI	t_{58}	*P*-value
Primary outcomes							
SCORE 'A-1'	IHM (*n*=30)	7.80±0.85	2.57±2.32	−5.83, 0.44	−6.71, −4.94	−13.17	<0.001*
	PLACEBO (*n*=30)	8.07±0.91	8.40±0.72				
SCORE 'A-2'	IHM (*n*=30)	7.93±0.74	2.33±2.35	−5.43,0.47	−6.38, −4.48	−11.45	<0.001*
	PLACEBO (*n*=30)	7.33±0.96	7.77±1.10				
SCORE 'A-3'	IHM (*n*=30)	7.43±1.14	2.07±2.21	−5.60,0.45	−6.50, −4.69	−12.43	<0.001*
	PLACEBO (*n*=30)	7.07±0.79	7.67±1.09				
Secondary outcomes							
SCORE 'B'	IHM (*n*=30)	254.27±61.89	113.73±83.80	−106.87,17.94	−142.77, −70.96	−5.96	<0.001*
	PLACEBO (*n*=30)	218.33±51.39	220.60±51.30				

SCORE 'A-1': VAS for pain; SCORE 'A-2': VAS for stiffness; SCORE 'A-3': VAS for loss of function; SCORE 'B': OAKQOL; SD: Standard deviation; df: Degree of freedom; t_{58}: t score at 58 degrees of freedom. IHM: Individualised homoeopathic medicine. **P* value calculated by Unpaired t-tests; $P<0.05$ considered statistically significant

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 113.73 ± 83.79 ($t = 10.30$, df = 29) and in the placebo group from 218.33 ± 51.39 to 220.60 ± 51.29 ($t = −3.45$, 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, $t = −5.96$, 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.

Table 5: List of the most frequently prescribed medicines at baseline between groups (*N*=60)

Name of the medicine	IHMs group (*n*=30); *N* (%)	Placebo group (*n*=30); *N* (%)
Rhus toxicodendron	9 (30)	9 (30)
Medorrhinum	7 (23.33)	7 (23.33)
Bryonia alba	7 (23.33)	5 (16.67)
Syphilinum	3 (10)	3 (10)
Ruta graveolens	1 (3.33)	1 (3.33)
Gnaphalium	1 (3.33)	1 (3.33)
Causticum	1 (3.33)	1 (3.33)
Arnica montana	1 (3.33)	1 (3.33)
Sulphur	0 (0)	2 (6.67)

IHM: Individualised homoeopathic medicine

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-

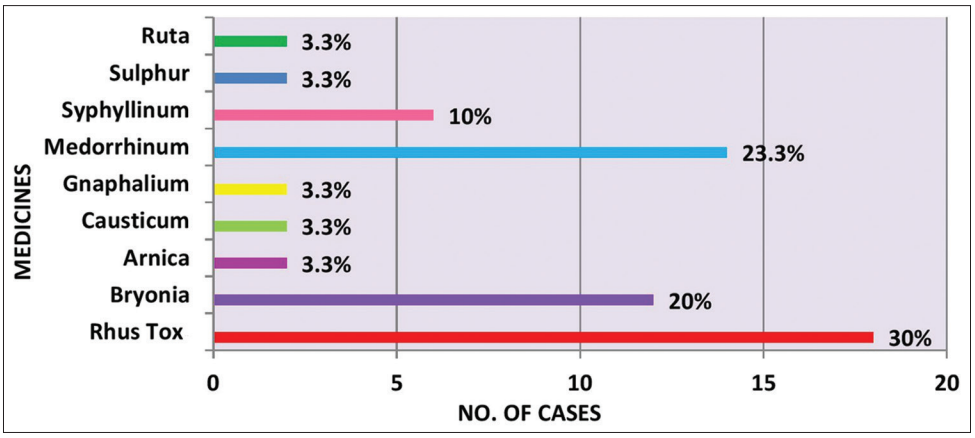

Figure 2: Frequently prescribed homoeopathic medicines at baseline in both groups

Table 6: Indication of frequently prescribed homoeopathic medicines

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

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 flourica* 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 lastly; 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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Conflicts of interest

There were no conflicts of interest.

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Médecine homéopathique individualisée contre placebo dans la gestion de la douleur liée à l'arthrose du genou et de la hanche: un essai contrôlé randomisé en double aveugle

Contexte: L'arthrose est une maladie dégénérative évolutive affectant les grosses articulations porteuses. La gravité des symptômes varie selon les individus, tandis que la douleur et la raideur sont les plaintes les plus gênantes. Les médicaments homéopathiques ont le potentiel de gérer les épisodes douloureux.

Objectif : Évaluer l'effet de la médecine homéopathique individualisée dans la prise en charge de la douleur liée à l'arthrose du genou et de la hanche.

Méthodes: Un essai prospectif, en double aveugle, randomisé (1:1), contrôlé par placebo, a été mené sur 60 personnes souffrant d'arthrose à R.B.T.S. Gouvernement. Collège et hôpital de médecine homéopathique, Muzaffarpur. L'EVA pour la douleur (Score-A-1), la raideur (Score-A-2) et la perte de fonction (Score-A-3) étaient les principaux critères de jugement et l'échelle OKHQOL (Score-B) était le critère de jugement secondaire. Les résultats ont été mesurés au départ et après 3 mois. Une analyse comparative a été effectuée pour détecter les différences entre les groupes. L'analyse intra et inter-groupes a été réalisée respectivement par des tests t appariés et non appariés.

Résultats: Des résultats statistiquement significatifs ont été observés dans les critères de jugement intra et intergroupes ($p < 0,05$, à 95 % IC). Les différences de groupe dans le score-A-1 (différence moyenne : -5,83, IC à 95 % -6,71 à -4,94, $p<0,001$), le score-A-2 (différence moyenne : -5,43, IC à 95 % -6,38 à -4,48). , $p<0,001$), Score-A-3 (différence moyenne : -5,60, IC à 95 % -6,50 à -4,69, $p<0,001$) et dans le score B (différence moyenne : -106,87, IC à 95 % -142,77 à - 70,96, $p<0,001$) étaient statistiquement significatifs après 3 mois. Cependant, l'amélioration était bien meilleure dans le groupe IHM que dans le groupe placebo. Les médicaments fréquemment indiqués étaient Rhus toxicodendron, Medorrhinum, Bryonia et Syphilinum.

Conclusion: Cette étude montre que les médicaments homéopathiques individualisés peuvent améliorer la douleur dans l'arthrose du genou et de la hanche, ainsi que la qualité de vie.

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

Hintergrund: Arthrose ist eine fortschreitende, degenerative Erkrankung, die große, das Gewicht tragende Gelenke betrifft. Die Schwere der Symptome variiert von Person zu Person, wobei Schmerzen und Steifheit die lästigsten Beschwerden sind. Homöopathische Arzneimittel haben das Potenzial, Schmerzepisoden zu lindern. **Zielsetzung:** Bewertung der Wirkung von individualisierten homöopathischen Arzneimitteln bei der Behandlung von Schmerzen bei Knie- und Hüftarthrose, **Methoden:** Eine prospektive, doppelblinde, randomisierte (1:1), placebokontrollierte 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 und die OKHQOL-Skala (Score-B) die sekundären Endpunkte. Die Ergebnisse wurden bei Studienbeginn und nach 3 Monaten gemessen. Um Gruppenunterschiede festzustellen, wurde eine vergleichende Analyse durchgeführt. Die Intra- und Intergruppenanalyse erfolgte mittels gepaarter bzw. ungepaarter t-Tests. **Ergebnisse:** Sowohl bei den Intra- als auch bei den Intergruppen-Ergebnissen wurden statistisch signifikante Ergebnisse festgestellt ($p<0,05$, bei 95% CI). Die Gruppenunterschiede in Score-A-1 (Mittlere Differenz: -5,83, 95% CI -6,71 bis -4,94, $p<0,001$), Score-A-2 (Mittlere Differenz: -5,43, 95% CI -6,38 bis -4,48, $p<0,001$), Score-A-3 (Mittlere Differenz: -5. 60, 95% CI -6,50 bis -4,69, $p<0,001$) und in Score-B (Mittlere Differenz: -106,87, 95% CI -142,77 bis -70,96, $p<0,001$) 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.

घुटने और कूल्हे के ऑस्टियोआर्थराइटिस के दर्द के उपचार में वैयक्तिकृत होम्योपैथी दवा बनाम प्लेसिबो: डबल-ब्लाइंड, आकस्मिक नियंत्रित परीक्षण

पृष्ठभूमि: ऑस्टियोआर्थराइटिस समय के साथ-साथ बढ़ने वाला, अपकर्शी रोग होता है, जो कि भार वहन करने वाले बड़े जोड़ों को प्रभावित करता है। दर्द और अकड़न सबसे अधिक परेशान करने वाले लक्षण होते हैं और लक्षणों की तीव्रता सबसे भिन्न होती हैं | होम्योपैथी दवाओं में दर्द से राहत देने की क्षमता होती है। **उद्देश्य:** घुटने और कूल्हे के ऑस्टियोआर्थराइटिस के दर्द के उपचार में वैयक्तिकृत होम्योपैथी दवा के प्रभाव का मूल्यांकन करना। **विधियां:** आर.बी.टी.एस राजकीय होम्योपैथी मेडिकल कॉलेज एवं अस्पताल, मुजफ्फरपुर में ऑस्टियोआर्थराइटिस से पीड़ित 60 लोगों पर एक संभावित, डबल-ब्लाइंड, आकस्मिक (1:1), प्लेसिबो-नियंत्रित परीक्षण किया गया। दर्द के लिए VAS (स्कोर-A-1), अकड़न (स्कोर-A-2) और लॉस-ऑफ-फंक्शन (स्कोर-A-3) प्राथमिक परिणाम थे और OKHQOL स्केल (स्कोर-B) द्वितीयक परिणाम था। परिणामों को बेसलाइन पर और 3 माह के बाद मापा गया। सामूहिक अंतर का पता लगाने के लिए तुलनात्मक विश्लेषण किया गया।

युग्मित और अयुग्मित टी-परीक्षणों द्वारा क्रमशः इंट्रा और इंटर-ग्रुप विश्लेषण किया गया। **परिणाम:** इंट्रा और इंटर-ग्रुप दोनों ही विश्लेषणों में सांख्यिकीय रूप से महत्वपूर्ण परिणाम देखे गए (p<0.05, 95% CI)। स्कोर-A-1 (औसत अंतर: -5.83, 95% CI -6.71 से -4.94 तक, p<0.001), स्कोर-A-2 (औसत अंतर: -5.43, 95% CI -6.38 से -4.48 तक, p<0.001), स्कोर-A-3 (औसत अंतर: -5.60, 95% CI -6.50 से -4.69 तक, p<0.001) और स्कोर-B में (औसत अंतर: -106.87, 95% CI -142.77 से -70.96 तक, p<0.001) सामूहिक अंतर 3 माह के बाद सांख्यिकीय रूप से महत्वपूर्ण रहे। प्लेसिबो समूह की तुलना में आईएचएम (IHM) समूह में सुधार अधिक बेहतर रहा। *रहस टॉक्सिकोडेंड्रोन (Rhus Toxicodendron), मेडोरिनम (Medorrhinum), ब्रायोनिया (Bryonia)* और *सिफिलिनम (Syphilinum)* अक्सर संकेतित दवाएं रहीं। **निष्कर्ष:** इस अध्ययन से यह पता चलता है कि व्यक्तिगत होम्योपैथी दवाओं से घुटनों और कूल्हे के ऑस्टियोआर्थराइटिस के दर्द के साथ-साथ जीवन की गुणवत्ता में सुधार लाया जा सकता है।

Medicina homeopática individualizada frente a placebo en el tratamiento del dolor de la artrosis de rodilla y cadera: Un ensayo doble ciego, aleatorizado y controlado

Antecedentes: La artrosis es una enfermedad degenerativa y progresiva que afecta a las grandes articulaciones que soportan peso. La gravedad de los síntomas varía de una persona a otra, pero el dolor y la rigidez son las molestias más frecuentes. Los medicamentos homeopáticos pueden tratar los episodios de dolor. **Objetivo:** Para evaluar el efecto de la medicina homeopática individualizada en el tratamiento del dolor de la osteoartritis de rodilla y cadera, **Métodos:** Se realizó un ensayo prospectivo, doble ciego, aleatorizado (1:1) y controlado con placebo en 60 personas que padecían osteoartritis en el R.B.T.S. Gobierno de la Facultad de Medicina y Hospital Homeopático de Muzaffarpur. Los resultados primarios fueron la EAV para el dolor (puntuación A-1), la rigidez (puntuación A-2) y la pérdida de función (puntuación A-3), y el resultado secundario fue la escala OKHQOL (puntuación B). Los resultados se midieron al inicio del estudio y al cabo de 3 meses. Se realizó un análisis comparativo para detectar diferencias entre grupos. Los análisis intragrupo e intergrupo se realizaron mediante pruebas t emparejadas y no emparejadas, respectivamente. **Resultados:** Se observaron resultados estadísticamente significativos tanto en los resultados intragrupo como en los intergrupos (p<0,05, con un IC del 95%). Las diferencias entre grupos en la Puntuación-A-1 (Diferencia media: -5,83; IC del 95%: -6,71 a -4,94; p<0,001), la Puntuación-A-2 (Diferencia media: -5,43; IC del 95%: -6,38 a -4,48; p<0,001), la Puntuación-A-3 (Diferencia media: -5. 60, IC del 95%: -6,50 a -4,69, p<0,001) y en la puntuación B (diferencia media: -106,87, IC del 95%: -142,77 a -70,96, p<0,001) fueron estadísticamente significativas después de 3 meses. Sin embargo, la mejoría fue mucho mejor en el grupo IHM que en el grupo placebo. Los medicamentos frecuentemente indicados fueron Rhus toxicodendron, Medorrhinum, Bryonia y Syphilinum. **Conclusión**: Este estudio demuestra que los medicamentos homeopáticos individualizados pueden mejorar el dolor en la artrosis de rodilla y cadera, así como la calidad de vida.

个体化 势 法 物与安慰 治 膝 和 骨 炎疼痛的比 ：一 双盲、随机对照 .

背景：骨 炎是一种 行性退行性疾病，影响大型承重 。症状的 重程度因个体而异，而疼痛和僵硬是最麻 的抱怨。 势 法 物有可能控制疼痛 作。

目的： 价个体化 势 法 物治 膝 骨 炎的 效。

方法：在 穆扎夫法尔普尔 R.B.T.S.政府 势 法医学院和医院对60名骨 炎患者 行前瞻性、双盲、随机（1:1）安慰 对照 。疼痛（ 分A-1）、僵硬（ 分A-2）和功能 失（ 分A-3）的VAS是主要 果，OKHGOL量表（ 分-B）是次要 果。在基 和3个月后 量 果。 行比 分析以 差异。 内和 分析分别通过配对和非配对t 行。 果：在 内和 果中均 察到具有 学意义的 果（在95%置信区 ，p<0.05）。三个月后，各 在 分A-1（平均差异：-5.83，95%CI-6.71至-4.94，p＜0.001）、 分A-2（平均差异 -5.43，95%CI-6.38至-4.48，p＜001）、 分A-3（平均差值：-5.60，95%CI-6.50至-4.69，p＜0.001%）和 分-B（平均差值 -106.87 ，95%CI-142.77至-70.96，p＜.001）方面的差异具有 学意义。然而，IHM 的改善情况比安慰 要好得多。

常 的用 有毒瘤 Rhus toxidendron、Medorrinum、Bryonia和Syphilinum。 ：本研究表明，个体化的 势 法 物可以改善膝 和 骨性 炎的疼痛，并提高生活 量。