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Review Article

EFFICACY OF HOMOEOPATHIC MEDICINE IN THE TREATMENT OF OSTEOARTHRITIS: A SYSTEMATIC REVIEW

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ABSTRACT

Introduction: Osteoarthritis is a non-inflammatory heterogeneous group of degenerative joint disease. Homoeopathic remedy has encountered rheumatological problems very well. The main aim of this systemic review was to evaluate, specify and pinpoint the findings of all relevant individualised studies, thereby making the available evidence more accessible to decision-makers. **Materials & Methods:** An intensive search of RCT clinical research manuscripts published between 2000 and 2022 was done under various databases and it ensured that all papers belong to peer-reviewed journals. The data items were extracted by following points like publication years, population, interventions and comparator (Verum vs control), outcomes, methods, overall result and manufacturer of Verum. The five-point Jadad scoring system was used to assess the methodological quality of the selected trials with increasing scores indicating a higher quality. Whereas the null hypothesis in this systematic review was that individualized homoeopathic medicine had no impact. **Results:** A total of 56 experimental and controlled clinical trials were identified to be screened. After complete screening, the proper number of eligible papers was 12 and finally selected 08 RCT with a double-blind peer-review published paper. The studies maintain total number of patients of 1,891 and after dropping out 1,628 patients eagerly continued. The 08 studies focused on knee joints and lower back pain. **Conclusion:** In this study, we clearly understood that homoeopathic combination formulas work well on OA. Individualized Homoeopathic remedy was not effective due to insufficient trial reports. It's also noticeable that homoeopathic combinations may have some adverse drug reactions. So, we need proper evidence for individualized homoeopathic medicine to say it works properly. It's our duty to uptake trial testing continuously for the betterment of homoeopathy. However, more research is needed to completely evaluate and validate the efficacy or inadequacy of therapy with OA.

INTRODUCTION

Osteoarthritis [osteo+ arthr+ itis] is a non-inflammatory heterogeneous group of degenerative joint disease seen mainly in older persons, characterized by degeneration of the articular cartilage, hypertrophy of bone at the margins, and changes in the synovial membrane. It is accompanied by pain, usually after prolonged activity, and stiffness, particularly in the morning or inactivity[1]. Osteoarthritis is also called "degenerative arthritis", "hypertrophic arthritis", and "degenerative joint disease". The prevalence of OA rises progressively with age, such that by 65 years 80% of people have radiographic evidence of OA, though only 25-30% are symptomatic [1,2]. The knee and hip are the principal

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large joints involved, affecting 10-25% of those aged over 65 years. Even for joints less frequently targeted by OA, such as the elbow or ankle [1,2,3]. OA remains the most common cause of arthritis. The genetic factor is also responsible for OA, especially for hip and knee. Knee OA is prevalent in all racial groups but hip, hand, and generalized OA are particularly prevalent in caucasians [1,2,3]. OA is more prevalent and more commonly symptomatic in women, except at the hip where men are equally affected. Osteoarthritis is the second most common rheumatologic problem and it is the most frequent joint disease with a prevalence of 22% to 39% in India[1,2,3,4]. Occupational or competitive sports trauma is a recognized predisposing factor and mainly affected farmers (hip OA), miners (knee OA) and professional footballers (knee OA). Conservative or conventional drug therapy for OA successfully relived the pain but side-by-side prolonged medication has some adverse drug reaction to gastrointestinal, cardiovascular and respiratory systems [5].

Complementary and alternative medicine has encountered rheumatological problems very well. Many patients use CAM therapies including homoeopathy to prevent, control and manage the pain of rheumatologic conditions [5,6]. However, scientific research has not enough to support the CAM system. Reviewers do not maintain proper data access or may be maintained some bias. Few low-poten-homeopathichic complexes in the randomised controlled trials seemed to possess significant effects in OA [7,8], but the potential of individualised homoeopathy remained untested. Hence, based on small to moderate effect sizes for the wide range of symptomatic treatments, conventional medicine in a personalized approach remains the mainstay of treatment [8]. The main aim of this systemic review was to evaluate, specify and pinpointed the findings of all relevant individualised studies, thereby making the available evidence more accessible to decision-makers.

MATERIALS AND METHODS

Eligibility Criteria: There were no restrictions regarding language or age group in this systematic review**.** These trials were eligible for comparison homeopathy applied for treatment of OA with placebo or medicinal therapies and an intensive search of clinical research manuscripts published between 2000 and 2022 was done for further systematic review and it ensured that all papers belong to peer-reviewed journals. In this systematic review, we preferred reporting items according to (PRISMA) guidelines [8,9].

Search Strategy

Data Sources: Different electronic bibliographic databases like MEDLINE (via PubMed), Cochrane Central Register of Controlled Trials (CENTRAL), CINAHL (EBSCO), Google Scholar, EMBASE (Elsevier), HomInform (Glasgow Homeopathic Hospital), Library of Central Council for Research in Homoeopathy, etc, the MeSH and non-MeSH search terms applied were keywords 'osteoarthritis', 'osteoarthrosis', 'gonarthrosis', 'homeopathy', 'homoeopathy', 'alternative medicine' and 'complementary medicine'.

Study Selection: Studies were limited to randomised controlled trials. Comparative studies of one homeopathic treatment measured against another active drug were included. There was no restriction regarding form or mode of application of the homeopathic treatment. Only RCTs of humans were included. We accepted those RCT papers are published under peer-reviewed Journals [9,10].

Data Extraction and Items: Data were extracted by a two (TS & SD) reviewer and checked by third (AS) reviewer. The data items were extracted by following points like publication years, population, interventions and comparator (Verum vs control), Outcomes, Methods, Overall result and manufacturer of Verum. The five-point Jadad scoring system was used to assess the methodological quality of the selected trials with increasing scores indicating a higher quality [10,11].

Selection Process: There are 3 reviewers screened each record (title/abstract). In between them, one is study investigator and who investigated individual screen record after we summarise the data.

Data Collection Process: Standardise data extraction from the Controlled Clinical Trials by the reviewers and provided consistency in the review, reduced bias, improving quality of study independently [11,12].

Data Items & Quality assessment: Data must be extracted on the bases of following points: Patients number, Intervention, Control group, Outcomes, Study design, Trial methodological quality was assessed using the standard scoring system developed and validated by Jadad et al, (maximum score 5; five items; Yes: 1; No: 0) [13] with items on random allocation, double-blinding and description of dropouts and withdrawals. Also maintained result with P-values. These tools use to access risk of bias in this study [14].

Critical Appraisal of Individual Source of Evidence: A descriptive summary was deduced from each study using the standardised data extraction form focusing on population recruited, interventions and comparator used, outcome measures, methods adopted, methodological scorings and overall result.

Charting the data: Data captured were (a) Year of publication and citation, (b) Author, (c) Patients (d) Intervention (f) Control group, (g) Outcomes, (h) Study Design & method, (i) Scoring, and (j) Overall results. The data were organized systematically in a

spreadsheet and was discussed among all authors periodically [13,14].

RESULTS

Study Selection and Characteristics: An intensive search on clinical research manuscripts published between 2000 and 2022 was done for further systematic review. Total 56 experimental and controlled clinical trials were identified to be screened. After complete screening, the proper number of eligible papers was 12 and finally selected 08 RCT with a double-blind peer-review published paper.

Table 1: Assessment of manuscript contents by the Jadad scale [Three assessment areas were given a score between 1 and 2, leading to a maximum of 5 points](0–5) [14,15]

Parameters	Points		Measures
Randomization	2	+1	Detailed information is given as follows: Point if randomization is mentioned
		+1	Additional point if the method of randomization is appropriate.
		-1	Point if the method of randomization is inappropriate
Blinding	2	+1	Point if blinding is mentioned
		+1	Additional point if the method of blinding is appropriate
		-1	Point if the method of blinding is inappropriate
Withdrawals	1		Point if the number and the reasons for withdrawal in each group are stated

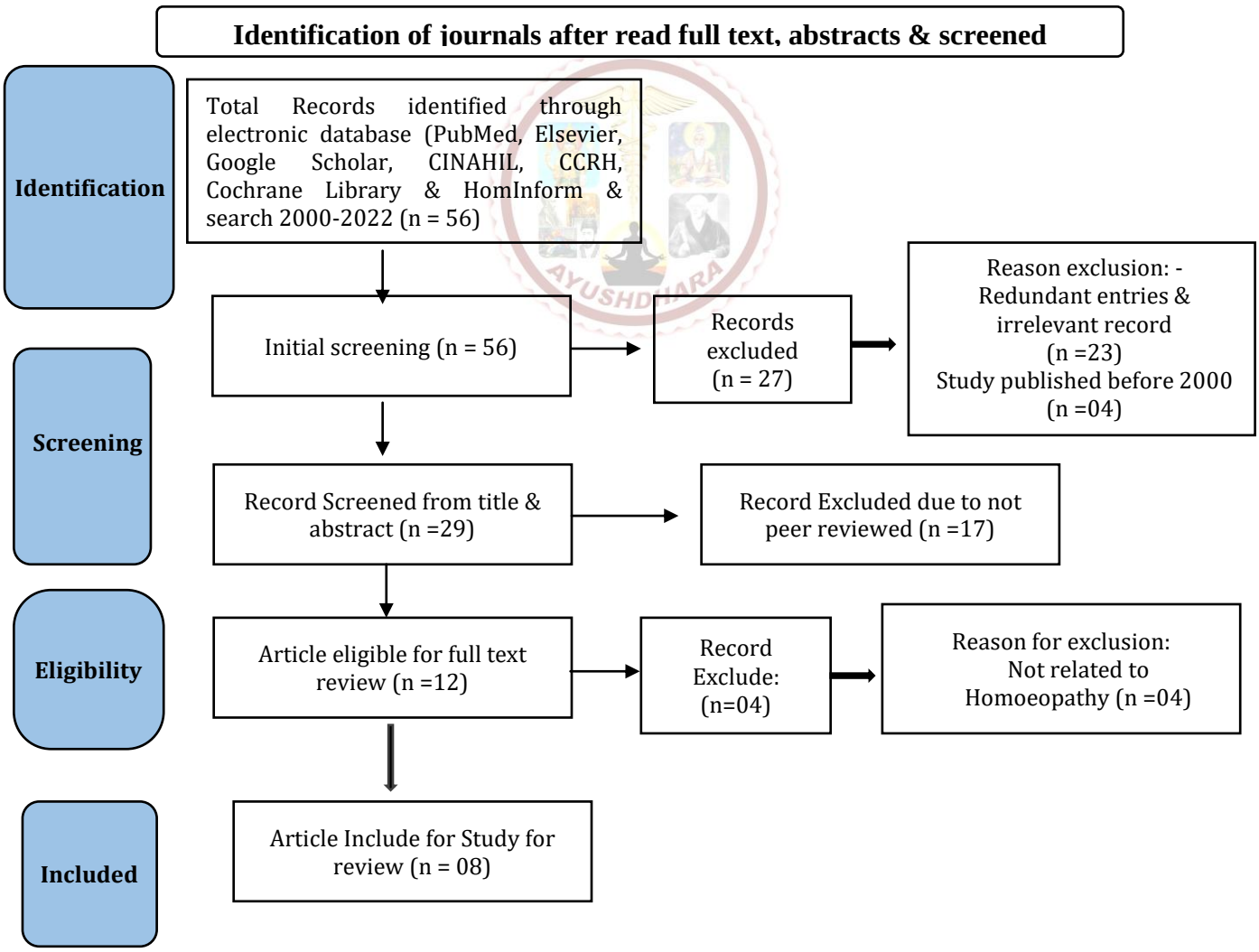

Figure 1: **Flowchart of the selected overall study design**

Table 1: Overview of clinical trials of homoeopathy in osteoarthritis [16,17]

Sl. No. & Author	Publication Year	Population	Interventions & comparator (Verum vs control)	Outcomes	Methods	Jadad score	Overall result	Manufacturer of Verum
		1.Number 2.Included/ analysed Condition 3.Demographics 4.Setting	1.Homoeopathy (Verum Group) 2. Control Group	1. Overall assessment 2. Patients assessed Globally as improved	1. Allocation to groups 2. Blinding 3. Concealment of allocation 4. Selection bias after allocation 5. Duration of observation			Homoeopathic Companies names
01) Van Haselen et.al	2000	a)184/172 b) Knee joint, c) 74% female & 26% male, mean age 64.2 years, mean weight 80.3 k.g d) London, UK	a) SRL® gel Composition (Symphytum officinale (comfrey), Rhus Toxicodendron (Poision ivy) & Ledum palustre (marsh tea)}. 8 hourly for 4 weeks. b) Feldene® gel (piroxicam contains 0.5%), 8 hourly for 4 weeks.	a) SRL® gel pain reduction 16.5 mm VAS & Feldene® gel pain reduction 8.1mm VAS. 95% Confidence interval 0.8- 15.9, b) SRL® group 55/92; Feldene® group 48/92	a) Randomised, b) Double-blind, c) Coded drugs, d) Unlikely, e) 4 weeks	05	Positive and significant (P = 0.036)	a) SRL® gel: -VSM Geneesmiddelen (The Netherlands) & Under guidelines by official German Homoeopathic Pharmacopoeia. b) Piroxicam gel (Feldene®):- Pfizer Ltd UK
02) Birnesser et.al	2003	a) 592\592, b) OA Knee Stages I and II (Richter's classification) c) Not mentioned. d) Germany	a) Zeel® comp. N tablets containing *Arnica montana*, *Sanguinaria canadensis*, *Rhus tox*, *Solanum dulcamara* and *sulphur*; one tablet three to five times a day for 10 weeks, b) COX-2 inhibitors Celebrex® (Celecoxib 100 or 200 mg) capsules and Vioxx® (Rofecoxib 12.5 or 25 mg) tablets	**a)** Zeel® comp. N was not less effective than COX-2 inhibitors; tolerability higher in homoeopathy group. **b)** 255/323 (79%); 231/269 (86%); difference between groups non- significant (P= 0.16)	a) Non-randomised b) Open c) None d) Very likely e) 10 weeks	00	Positive; P-value not Reported properly & need to be statistically significant.	Not mention

03) Koley et. al	2015	a) 98/60(dropped out 06), b) OA Knee, c) Mean age 57.3 yrs, Female 81.6%, Male 18.3%, Mean Weight 61.25 kg. d) West Bengal, India.	a) Individualized homeopathic intervention (Bryonia alba (23.2% and 22.4%), Rhus Toxicodendron (14.3% and 20.7%), Calcarea carbonica (8.9% and 3.4%), Arnica montana (7.1% and 3.4%), and Natrum muriaticum (5.4% and 5.2%), (taken orally on clean tongue, consisted of 4 cane sugar globules of size 30, and moistened with a single drop of indicated medicine prepared and preserved with 88% v/v ethanol.) b) Placebo (Same non medicated globules)	**a)** Homoeopathic medicine Group reduction of pain VASs (–15.1; 95% CI, –45.3, 15.1; P < .0001, 2-tailed, paired t test), b) Placebo Group reduction in pain VAS (–10.8; 95% CI, –36.7, 15.1; P ¼ .0001)	a) Randomised, b) Double-blind, c) Coded drugs, d) Unlikely, e) 2 weeks	05	Negative, Osteoarthritis Research Society International scores in both groups over 2 weeks (P < .05); however, group differences were not significant (P > .05).	GMP-certified firm: SBL Pvt Ltd. (Both Groups)
04) Pellow Janice et.al	2016	a) 40/30, b) OA lower back, c) 45 Years to 75 Years (Adult, Older Adult), d) University of Johannesburg, South Africa.	a) Homeopathic complex and physiotherapy Homoeopathic complex (Arnica montana 6CH, Bryonia alba 6CH, Causticum 6CH, Kalmia latifolia 6CH, Rhus toxicodendron 6CH and Calcarea fluoride 6CH), b) Placebo and physiotherapy Both Group taken 2 tablets on tongue before 20 minutes of meal (2tab, BDAC,6 weeks)	a) Homoeopathic Group: - VAS Without Palpation p<0.001 [χ2 (3, n=15) =42.064], VAS with Palpation p<0.001 [χ2 (3, n=15) = 41.596]; b) Placebo group: - VAS Without Palpation p=0.002 [χ2 (3, n=15) = 14.831]. VAS With Palpation p<0.001 [χ2 (3, n=5) = 23.974].	a) Randomised, b) Double blind, c) Coded drugs not mentioned, d) Unlikely, e)0,2,4, 6 weeks	04	The p-values, at a 95% confidence interval, were interpreted as follows: p<0.05 was statistically significant. The Wilcoxon Test P<0.016 was statistically significant.	CoMed (Pretoria, Gauteng, South Africa) & GMP certified.

05)Widrig et. al	2007	a) 204/198 b) OA hand c) Mean age 64 yrs; female 74% d) Switzerland	a) A. Vogel® Arnica Gel (arnica tincture 50 gm / 100 gm gel; drug-to-extract ratio of the tincture 1:20); 8 hourly for 3 weeks; b) Optifen® Gel Ibuprofen gel 5%; 8 hourly for 3 weeks	a) Pain VAS reduced significantly in both groups; difference in reduction non-significant b) 71/89 (80%); 64/85 (75%)	a) Randomised, b) Double blind, c) Coded drugs, d) Unlikely, e) 3 weeks	05	Negative; *P*-value not reported	Bioforce AG
06)Beer et.al	2012	a)248/221 (Dropout 29) 137 completed the study. b) OA lower back c) age 18 to 75 years (male, female) d) Germany	a) Homoeopathic composition (calendula Q-4.5gm, Condurango D2 0.1gm, Phytolocca D2 0.2 gm, Carduus marianus D1 0.2 gm, Chelidonium D2 0.5 gm, Hydrastis Q- 0.1 gm, Leptandra Q- 0.3 gm, Taraxacum Q-8 gm, Echincea Q- 0.3 gm, Lycopodium D2 0.1 gm, Sanguinaria Q- 0.1 gm, Arsenicum album D8 1.0 gm) b) Placebo (verum in colour, taste & form but did not contain any pharmacologically active substance. 86% ethanol, distilled water, saccharum tostum (1;1) & riboflavin phosphate sodium. (Both Groups received 10 drops, TDS, 15 weeks + non-drug interventions)	a) Verum group Pain VAS(n=102) 5.8/6.0 b) Control group-VAS(n=85) 6.0/ 6.1	a) Randomised, b) Double blind, c) Coded drugs, d) Unlikely, e) 3 weeks	05	Increase in the intention-to-treat-analysis (verum: 6.6 vs. placebo: 3.4; p = 0.11) not statistically significant and Increases significantly in the per-protocol-analysis (verum: 9.4 vs. placebo: 4.1; p = 0.029) Positive statistically significant.	Not Mentioned
07) B. Brinkhaus et al.	2006	a)482/319 b) Suffering knee disease that necessitated arthroscopic surgery. C) both	a) *Arnica. Montana 30* (German Homoeopathic Pharmacopoeia) 5 globs, 2houre before surgery. Postoperatively, on the day of the surgery, patients were given 3×5 globules at 3 h intervals	a) CLR'S Verum Group pain VAS (Primary SD-3.43 (2.68)} b) CLR'S Control Group Pain VAS	a) Randomised, b) Double blind, c) Coded drugs, d) Unlikely, e) preoperatively	05	Positive for CLR (cruciate ligament reconstructio n) p VALUE 2 side=0.019,	Deutsche Homoeopathische Union (DHU) in Karlsruhe, Germany, GMP Certified

		genders, age 18—75 years. d) Bavaria, Germany	after the recovery phase. Starting on the second postoperative day, five globules three times a day until the last scheduled follow-up examination. b) Placebo (Administrated same way)	(Primary SD-4.75 (2.78)}	and postoperative days 2, 3, 5, 8 and 11.		ART P-value (2 side) =0.204 & AKJ P value (2 side) = 0.184	
08) R. Gmunder et al.	2002	a) 43/36 b) Chronic lower back pain, average 51.9 years c) 18 to 70 years (13 male & 26 female), & d) Germany	a) Homoeopathic Group (remedy name not mentioned) b) Physiotherapy Group Control group not mentioned	a) Homoeopathic group's VAS before/ after P= 0.0042(significant) b) Physiotherapy group VAS(B/A) P=0.0095(Significant)	a) Randomised b) Blinding not mentioned, c) Not mentioned code drug d) Likely e) 8weeks	03	Positive, according VAS & both groups, have statistically significant (H(P)=0.0042 & P(P)=0.0095	Not mentioned
Mean Value						**04**		

Individual Study Character and results: We are screening individual RCT papers followed by maintained risk of bias. The proper methodology is measured to minimize the bias with the help of the Jaded Scale. So, in these circumstance Koley et al. [18,19,20], Van Haselen et.al, Widrig et. al, Beer et.al & B. Brinkhaus et al. are well described their studies. In between them, koley et al. article was tremendously well performed [21,22]. *Janice Pellow et.al* & *R. Gmunder et al*. both are moderately maintained or scored, side by side they have not followed the proper guidelines of RCT [23]. The studies by Birnesser et.al was followed the very poorest methodology for RCT. There was no sign of a Homoeopathic single intervention used against the placebo except koley et al. trial. The "complexes" and "combination formulae" were used against the placebo in the majority of the selected study [23]. The studies maintain total participate number of patients 1,891 and after dropping out 1,628 patients eagerly continued. The 08 studies were focusing into knee joints and lower back pain. All studies were randomised, double blinding & coded except two like Birnesser et.al & R. Gmunder et al.

DISCUSSION

The present review found consistent evidence that "complexes" and "combination formulae" were effective in the management of OA. We took eight clinical trials on OA in systematic review and only one study maintained individual homoeopathic remedy against a placebo, whereas the null hypothesis in this systematic review was that Individualized homoeopathic medicine had no impact [23]. The 08 studies focused on knee joints and lower back pain. All studies were randomised, double blinding and coded except two like Birnesser et.al & R. Gmunder et al. Koley et al. [23], Van Haselen et.al, Widrig et. al, Beer et.al & B. Brinkhaus et al. are well described their studies. The studies by Birnesser et.al was followed the very poorest methodology for RCT.

Scope and Limitation of Journals: As we know any systematic review was based on the RCT and we selected eight homeopathic RCTs after properly screening, eligible and including. Each and every trial have some scope and limitation, this thinks based on some group, reduction in VSA, WOMAC pain measuring on movement, duration of rest, stiffness and incidence of OA [24].

Van Haselen et.al journal properly maintained the inclusion and exclusion criteria, good clinical practitioner guidelines, and maintained proper guidelines for RCT. Author not mentioned whether comorbidity patients were added or not. The study protocol was primarily outcome measures were pain on walking during the previous 24 hours, recorded on a 100mm Visual Analogue Scale [23,24]. Secondary, Outcome measures were the number of uses of paracetamol during this study conduct. The author properly uses 95% confidence intervals in relation to the equivalence range. The overall assessment was analysed by the exact "Mann – whitney U-test" [24]. The assessment maintained 4 randomization software. In the masking section SRL® gel is brownish in colour and pine oil used for maintaining characteristic odour but this pine oil was adulterated or not adulterated or which company belong, is not mentioned. Overall, this article is shown evidenced enough for homoeopathic intervention can work on osteoarthritis [24,25]. *Heinz Birnesser et al* article is not followed the RCT's protocol. Inclusion and exclusion criteria are not mentioned properly. Patients evaluated their progress during the study with the help of a validated German version of the WOMAC Osteoarthritis Index [25,26]. Overall results were positive but statistical significance can't understand properly.

Koley et al. was a prospective, parallel arm, double-blind, randomized, and placebo-controlled, and it was conducted with well-maintained inclusion and exclusion criteria[27]. The procedures for discussion, conclusion, and statistical evaluation are thoroughly elaborated and they also follow the rules of GCP protocols[28]. They overall maintained the homoeopathic guidelines that are individualization followed by individual homoeopathic intervention applied to various patients of osteoarthritis. They followed VAS and although significant reductions were achieved in all the outcomes across the 2 groups, group differences were not significant (P > .05, 2-tailed) on any occasion [29]. Between the homeopathy and placebo groups, Bryonia alba (23.2% and 22.4%), Rhus toxicodendron (14.3% and 20.7%), Calcarea carbonica (8.9% and 3.4%), Arnica montana (7.1% and 3.4%), and Natrum muriaticum (5.4% and 5.2%) were the most frequently prescribed medicines, and the frequencies were comparable between groups as well (P> .05, 2-tailed) and they should not mention the potency.

Beer Von.A-M et al. was a well methodologically maintained a double blind, randomized, placebo control German paper [30]. In this trial mainly focussed on the chronic lower back pain and homoeopathic combination well performed instead of modern medicine. This point of view it's a scope in homoeopathy but it's also true homoeopathic combination also produces some side effect and this is the limitation [31]. The treatment was well tolerated (92.9% vs 95.4%). Pellow Janice et. al article is moderately followed the trial methodology but in hence it's a randomized, double-blind, placebo-controlled pilot study [31,32]. The study was compared

among homoeopathic combination and placebo with physiotherapy management. It's a good think that all case was measure by 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 but the limitation is homoeopathic combination mode of treatments [32,33]. We don't know there was some adverse effect present or not and the study conducted by a single physiotherapist and the sample size was very small. Mann-Whitney U test and independent samples t-test $p<0.05$ was statistically significant and Wilcoxon Test shown $p<0.016$ was statistically significant [34]. Widrig Reto et. al trial was randomised, double-blind study and here sample size was huge. The overall outcome was the same on both groups (*A.Vogel® Arnica Gel & Optifen® Gel Ibuprofen gel 5%)* and there were some adverse drug reaction happened in both groups, which was a limitation of the study [34].

Brinkhausa. B et. al was a three randomized, placebo-controlled, double-blind, sequential clinical study. It's mainly compared with arnica and placebo among postoperative patients. Hare arnica performed very well side by side the sample size was very big, that's why the probability of risk of bias was very low. In this study pain measuring scale was not properly mentioned, and how to manage comorbidity patients was not mentioned [34]. *R. Gmunder et al.* was a controlled, randomized prospective study but the study protocol was not maintained properly, the sample size was very small, the overall outcome was very poor result and homeopathy double-blind must be needed.

The protocol for this review was has not been preregistered with PROSPERO, so it is a limitation of this review and the sample size (n=08) less [35,36]. So, in the main analysis, therefore, limiting the sample size decreases the study's confidence level and increases the margin of error. We can't use Joanna Briggs proposed 13 criteria for evaluating the quality of randomization clinical trial trials [37].

CONCLUSION

In this study, we clearly understood that homoeopathic combination formulas work well on OA. Individualized Homoeopathic remedy was not effective due to insufficient trial reports. It's also noticeable that homoeopathic combinations may have some adverse drug reactions. So, we need proper evidence for individualized homoeopathic medicine to say it works properly. It's our duty to uptake trial testing continuously for the betterment of homoeopathy. However, more research is needed to completely evaluate and validate the efficacy or inadequacy of therapy with OA.

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