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Research Protocol

Nursing Section

Comparative Evaluation of Sesame Oil Massage, Epsom Salt Hot Water Application, and their Combination for Managing Knee Joint Pain in Homemakers: A Research Protocol

JAYA KHANDAR[1], ABHAY MUDEY[2], DEEPLATA MENDHE[3], ACHITA SAWARKAR[4]

ABSTRACT

Introduction: Knee pain is a common musculoskeletal disorder, particularly observed among homemakers who engage in prolonged standing and repetitive activities. The burden of knee pain significantly affects mobility, Quality of Life (QOL), and daily functioning. Osteoarthritis (OA) remains the leading cause of knee pain, and non-pharmacological interventions are increasingly being recognised as safe and effective alternatives to conventional treatments.

Need of the study: Homemakers, due to their daily household activities, have a higher tendency to develop knee pain, which often goes unaddressed because of financial constraints and limited access to healthcare. Prolonged use of pharmacological management for knee pain is associated with adverse effects, thereby necessitating alternative, cost-effective, and community-based interventions. Sesame oil is known for its anti-inflammatory and antioxidant properties, while Epsom salt, rich in magnesium sulphate, promotes muscle relaxation and circulation. Despite these potential benefits, limited research has compared their effectiveness when used individually and in combination. This study aims to fill this gap and provide evidence-based recommendations for the management of knee pain in homemakers.

Aim: To compare and evaluate the effectiveness of Epsom salt hot water application, sesame oil massage, and their combination for knee pain management among homemakers.

Materials and Methods: A three-arm parallel Randomised Controlled Trial (RCT) will be conducted from May 2024 to May 2026 in selected rural areas of the Wardha district, India. A total of 126 homemakers aged 40-60 years with mild to moderate knee pain will be randomly assigned to three groups of 42 participants each. Group A will receive sesame oil massage, Group B will receive hot water fomentation with Epsom salt, and Group C will receive a combination of both interventions. Outcome measures will include pain severity and functional status, assessed at baseline (Day 0) and after three weeks of intervention. Pain severity will be evaluated using the Visual Analogue Scale (VAS), and functional status will be assessed using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). For intergroup and intragroup comparisons, one-way ANOVA and paired t-tests, respectively, will be applied. Additionally, for pairwise comparisons, post-hoc Tukey's test will be used. Associations between demographic variables and intervention outcomes will be analysed using Pearson's Chi-square test. Statistical significance will be set at $p<0.05$.

Keywords: Musculoskeletal pain, Non-pharmacological treatment, Osteoarthritis, Rural population, Women's health

INTRODUCTION

The Global Burden of Disease 2019 data estimated that 1.71 billion people worldwide suffer from musculoskeletal disorders, including neck, back, and knee pain, rheumatoid arthritis, Osteoarthritis (OA), and fractures [1]. Among these, knee pain affects 46.2% of the global population (32.2% men and 58.0% women), significantly impacting daily activities, Quality of Life (QOL), and independence [2]. Risk factors for knee pain include female sex, low educational level, depression, obesity, ageing, previous injuries, and occupations involving knee-straining activities [2]. Moreover, knee OA is a chronic, age-related joint disorder affecting 22.9% of individuals over 40 years of age and ranks fourth in disability among women and eighth among men globally [3,4].

In India, OA ranks among the top five chronic diseases and is the second most common rheumatologic condition, with an incidence ranging from 22-39%. It is more prevalent in women than in men, and the incidence increases sharply with age [4].

Homemakers who engage in prolonged standing, repetitive physical activities, and other strenuous household tasks devote substantial time and effort to maintaining their homes. However, routine household chores often result in musculoskeletal pain, leading to physical impairment, loss of productivity, and increased healthcare utilisation [5]. Evidence also links physical exertion during work with musculoskeletal pain [1,6]. Both professional and domestic work can cause musculoskeletal discomfort due to inflammation of muscles, nerves, and soft tissues, affecting individuals across all ages, identities, and social groups [2].

According to the World Health Organisation (WHO), women comprise 67% of the global workforce, predominantly in the informal sector such as domestic work and agriculture [7]. This trend is observed in both developed and developing countries, with middle-income nations reporting a high prevalence of musculoskeletal pain among full-time homemakers due to household tasks [5]. For instance, studies have reported that homemakers in Italy experience musculoskeletal pain caused by domestic work [8]. Similarly, a recent study in Bangladesh found that 68.49% of women experienced body pain in the past year, and 50.68% were unable to perform daily activities due to musculoskeletal symptoms [9].

Prolonged standing, frequent bending, and heavy lifting impose mechanical stress on the knees, accelerating degenerative changes [10]. However, socio-economic barriers often limit homemakers' access to healthcare, leading to inadequate pain management and reduced quality of life [5]. Currently, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) are widely used for knee pain management [11]. Yet, prolonged NSAID use is associated with gastrointestinal,

cardiovascular, and renal complications [12]. Consequently, there is an urgent need to explore accessible, non-invasive, and cost-effective alternatives for pain management.

Traditional therapies such as hot water fomentation with Epsom salt and sesame oil massage have been used for centuries to relieve musculoskeletal discomfort [13-15]. Sesame oil contains bioactive compounds with anti-inflammatory and antioxidant properties that help reduce joint pain and stiffness [16], whereas Epsom salt, rich in magnesium sulphate, promotes muscle relaxation, improves circulation, and alleviates pain [13].

Despite anecdotal evidence supporting their benefits, there is a lack of well-designed clinical trials evaluating the effectiveness of these interventions in knee pain management. Furthermore, no study has systematically compared the effectiveness of Epsom salt therapy, sesame oil massage, and their combined use. This study aims to address this gap by providing empirical evidence on the role of these non-pharmacological approaches in alleviating knee pain among homemakers. If proven effective, these therapies could be incorporated into routine self-care practices, offering a practical, low-cost, and sustainable alternative for managing knee joint pain in homemakers.

REVIEW OF LITERATURE

Sesame oil, a pale-yellow extract from Sesamum indicum seeds (containing 45-54% oil), comprises 61.7% fat and 21.9% protein, and is rich in calcium and iron. It contains about 80% unsaturated fats. Sesame seeds are nutrient-dense and are regarded as the "crown of eight grains" and an "all-purpose nutrient bank" [16]. Askari A et al. found that, in comparison to diclofenac gel, topical sesame oil demonstrated a similar effect in improving function and reducing pain in patients with knee osteoarthritis (OA) [14]. Nasiri M and Farsi Z reported that light-pressure massage with sesame oil significantly reduced limb trauma pain, supporting its use as a low-cost, accessible, and safe complementary therapy [17].

Epsom salt baths are widely recognized for providing relief from arthritis-related knee pain. Soaking in warm salt water is a time-tested home remedy for knee pain. Findings have shown that it loosens joints, alleviates pain, and provides lasting effects beyond immersion. The heat relaxes muscles, relieves pain, induces vasodilation, boosts circulation, enhances mobility, and reduces joint stiffness [13]. Samayochitha K et al. found a significant reduction in knee pain among the elderly population when Epsom salt hot water was applied compared to plain hot water [18]. Similarly, Okram D et al. found that, compared to common salt fomentation, Epsom salt fomentation was more effective among the elderly for managing knee pain [13].

Sesame oil, rich in linoleic acid, is a traditional remedy with anti-inflammatory, antioxidant, and antibacterial properties [16]. In contrast, Epsom salt hot water therapy alleviates pain, inflammation, and congestion by improving blood flow, promoting muscle relaxation, and enhancing physical function [18]. Hence, this research aims to perform a comparative evaluation of the effectiveness of hot water fomentation with Epsom salt, sesame oil massage, and their combination in managing knee pain among homemakers.

To compare and evaluate the effectiveness of sesame oil massage, Epsom salt hot water application, and their combination for knee pain management among homemakers.

Primary objectives:

- To evaluate the effectiveness of sesame oil massage for knee pain management among homemakers.
- To evaluate the effectiveness of Epsom salt hot water application for knee pain management among homemakers.
- To evaluate the effectiveness of a combination of Epsom salt hot water and sesame oil for knee pain management among homemakers.

Secondary objectives: To compare the effectiveness of sesame oil massage, Epsom salt hot water application, and their combination for knee pain management among homemakers.

To analyse the association between intervention outcomes and selected demographic variables.

Null hypothesis (H_0): A combination of hot water application with Epsom salt and sesame oil massage is not significantly more effective for knee pain among homemakers compared to either intervention alone.

Alternate hypothesis (H1): A combination of hot water application with Epsom salt and sesame oil massage is significantly more effective for knee pain among homemakers compared to either intervention alone.

MATERIALS AND METHODS

This three-armed, parallel, Randomised Controlled Trial (RCT) will be conducted in a selected rural area of the Wardha district from May 2024 to May 2026. The study has been approved by the Institutional Ethical Committee (IEC) of Smt. Radhikabai Meghe Memorial College of Nursing, Sawangi (Meghe), Wardha, Maharashtra, India (Approval No.: DMIHER(DU)/Ph.D.Regn/2024/97), and the trial is registered in the Clinical Trial Registry of India (CTRI/2024/08/072182).

Before recruitment, the purpose and methodology of the study will be explained to each participant, and those meeting the inclusion criteria will be required to provide written informed consent. Participant confidentiality will be maintained throughout the study.

The study population will include homemakers from selected rural areas of the Wardha district, and the eligibility criteria will be as follows:

Inclusion criteria: Homemakers who are willing to participate and provide written informed consent. Homemakers aged between 40 and 60 years with mild to moderate knee joint pain due to OA.

Exclusion criteria: Homemakers with severe neuropathies, burns, blisters, or skin lesions on the joints; those with acute inflammation (e.g., acute appendicitis, tooth abscess); unconscious or mentally unstable individuals; homemakers with sensorineural deficits (e.g., diabetes mellitus, peripheral neuropathy); homemakers with complicated conditions (e.g., neuropathies, vascular compromise, or systemic lupus erythematosus); homemakers with mental illness; homemakers allergic to Epsom salt or sesame oil; and participants presenting with fever or high body temperature.

Sample size calculation: The formula $N=\{Z_{1-\alpha/2}*\sqrt{((r+1)*p*(1-p))}+Z_{1-\beta}*\sqrt{(p1(1-p1)+p2(1-p2))}\}^2/r*(p2-p1)^2$ was used for calculation of sample size [19,20] where N = minimum samples required for each group, alpha (α)=0.10 $\rightarrow Z_{1-\alpha/2} \approx 1.645$ represents the desired level of statistical significance, beta (β)=0.20 $\rightarrow Z_{1-\beta} \approx 0.842$ represents the desired power for 80%, P=(p1+p2)/(1+r)=(0.167+0.417)/(1+1)=0.292, P1=pain improvement to no pain category for Epson salt treatment=16.7%, P2=pain improvement to no pain category for combination of sesame oil and Epson salt treatment=41.7% (with 25% expected margin), at level of significance 5% and power 80%. With a clinically significant margin of 25%, the minimum sample size required is Numerator=$\{Z_{1-\alpha/2}*\sqrt{((r+1)*p*(1-p))}+Z_{1-\beta}*\sqrt{(p1(1-p1)+p2(1-p2))}\}^2=\{1.645*\sqrt{((2)*0.292*(1-0.292))}+0.842*\sqrt{(0.167(1-0.167)+0.417(1-0.417))}\}^2=2.491$, and Denominator=$r*(p2-p1)^2=1*(0.417-0.167)^2=0.062$. Hence, N=2.491/0.062=40. Minimum sample size needed for each group=40 however, the minimum sample size required per group is 40. Considering a 5% dropout rate, the sample size will be 42 per group.

Therefore, the total sample size required=3×42=126 homemakers.

Study Procedure

Recruitment and baseline assessment: Homemakers from selected rural areas of the Wardha district who are willing to participate will receive written details of the intervention (Participant

Information Sheet). They will be screened for eligibility and requested to provide written informed consent. Participants will be closely monitored for signs of weakness or faintness during the study.

Demographic details (age and body mass index) will be recorded. Baseline evaluation of pain severity will be conducted using the Visual Analogue Scale (VAS) [21] and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [22,23] for functional status assessment.

Intervention protocols:

Group A (Sesame Oil Massage): Each participant will receive a sesame oil massage, for which 10 ml of sesame oil will be indirectly heated by placing the bowl in hot water. The warm oil will then be applied to the entire knee joint using light, downward circular finger movements for 10 minutes, twice daily for three weeks. Care will be taken not to press too hard or cause discomfort. The technique will be applied to both knees.

Group B (Epsom Salt Hot Fomentation): Thirty grams of Epsom salt will be dissolved in one litre of hot water (maintained at a tolerable temperature). A clean cloth will be soaked in the solution to make a compress, which will be applied to the knee joint for 10–15 minutes, twice daily for three weeks. The compress will be replaced every 2–3 minutes to maintain warmth. Participants will be encouraged to perform slow knee movements during the application.

Group C (Combination Therapy): Participants will receive both therapies—10 ml of sesame oil massage (10–15 minutes, twice daily for three weeks) combined with hot fomentation using 5 grams of Epsom salt in hot water (10–15 minutes, twice daily for three weeks)—to evaluate the effect of combination therapy.

Participants will be recruited into groups using a purposive sampling method. To minimize bias, single blinding will be implemented, where outcome assessors and data analysts will be blinded to group assignments. Blinding of participants and intervention providers will not be feasible due to the distinct nature of the interventions.

Post-treatment, the excess oil will be wiped off, allowing the skin to absorb the remaining oil naturally. Participants will be advised to avoid immediate strenuous activities. The procedure details, pain levels, and participant feedback will be documented.

After ten days of intervention, pain severity will be reassessed using the VAS, and functional status will again be evaluated using the WOMAC Index.

Outcome measures:

Primary Outcome (VAS): Participants will indicate their pain level on a 10 cm line (0=no pain to 10=worst possible pain) [21].

Secondary Outcome (WOMAC Index): The WOMAC index consists of 24 items assessing pain, stiffness, and physical function [22]. The subscales demonstrate high reliability, with Intra-class Correlation Coefficients (ICCs) exceeding 0.8, indicating strong test-retest consistency. Each item is rated on a 5-point Likert scale, and total scores range from 0 to 96, with higher scores indicating greater stiffness, pain, and functional disability [22,23].

The study will obtain the necessary license or permission from the copyright holder, Professor N. Bellamy, to use the WOMAC Index, ensuring compliance with copyright requirements [22,24].

Data will be collected at baseline (Day 0) and post-intervention (after three weeks).

STATISTICAL ANALYSIS

All analyses will be conducted using IBM SPSS Statistics (Version 26) to ensure robust data processing and reporting. Descriptive statistics will be computed for demographic and baseline characteristics. Inferential analyses will include:

- Paired t-test-to compare pre and post-intervention scores within groups.
- One-way ANOVA-to compare post-intervention scores between groups.
- Post-hoc Tukey's test-to determine pairwise differences between groups if ANOVA results are significant.
- Pearson's Chi-square test-to assess associations between intervention outcomes and demographic variables (age and BMI).
- Multiple regression analysis-to identify predictors of pain reduction and functional improvement.
- The final conclusion will be drawn by comparing p-values with a level of significance set at 5% ($p<0.05$).

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PARTICULARS OF CONTRIBUTORS:
1. Assistant Professor, Department of Community Health Nursing, Smt. Radhikabai Meghe Memorial College of Nursing, DMIHER (DU), Sawangi (Meghe), Wardha, Maharashtra, India.
2. Professor, Department of Community Medicine, Jawaharlal Nehru Medical College, DMIHER (DU), Sawangi (Meghe), Wardha, Maharashtra, India.
3. Associate Professor, Department of Community Health Nursing, Smt. Radhikabai Meghe Memorial College of Nursing, DMIHER (DU), Sawangi (Meghe), Wardha, Maharashtra, India.
4. Assistant Professor, Department of Community Health Nursing, Smt. Radhikabai Meghe Memorial College of Nursing, DMIHER (DU), Sawangi (Meghe), Wardha, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Jaya Khandar,
Assistant Professor, Department of Community Health Nursing, Smt. Radhikabai Meghe Memorial College of Nursing, DMIHER (DU), Sawangi (Meghe), Wardha, Maharashtra, India.
E-mail: jayakhandar@gmail.com

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