

## Study of the Efficacy of *Moringa Oleifera* Roots Applied as a Poultice in the Symptomatic Treatment of Gonarthrosis

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### Abstract

**Introduction:** The roots of *Moringa oleifera* are widely used for arthralgia. The aim of this study is to evaluate the effectiveness of a poultice made from *Moringa oleifera* root powder in the symptomatic treatment of gonarthrosis. **Material and methods:** It was a randomized, double-blind study, controlled against placebo and against standard drug treatment in open, conducted in the rheumatology department of CNHU-HKM in Cotonou. The patients included in the study had an arthritic flare at the beginning of the study. Three parallel groups were formed, receiving respectively *Moringa oleifera* as a poultice on the knee; placebo as a poultice on the knee; and oral drug treatment. The primary outcome measure is based

on the calculation of the effect size for pain intensity. **Results and conclusion:** Sixty-five patients were randomized (*Moringa oleifera* = 35, Placebo = 30) and twenty-one were non-randomized (medication treatment = 21). The studied population was characterized by a female predominance of 92%, with an average age of 57.94 years. The results of the effect size calculation for pain intensity showed a standardized difference greater than 0.8 in the *Moringa oleifera* and placebo groups over a duration of 2 weeks ( $p < 0.0001$ ) on one hand, and in the *Moringa oleifera* and medication treatment groups over a duration of 3 months ( $p < 0.0001$ ) on the other hand. This study showed that *Moringa oleifera* roots could constitute a potential therapeutic alternative in flare-ups of gonarthrosis.

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**Keywords:** Gonarthrosis, Poultice, *Moringa oleifera*, efficacy

## Introduction

Knee osteoarthritis is a chronic pathology that mainly affects women, with a sharp increase in the post-menopausal period (Guillemin F, 2011). It is a source of disability due to the pain and functional impotence it causes. In Black Africa, its hospital frequency is 13.19% in Côte d'Ivoire and 8.55% in Benin (Zomalheto Z, 2014). Drug treatment for gonarthrosis is essentially symptomatic and long-lasting, and consists of analgesics, anti-inflammatories and possibly corticosteroid infiltrations (Zhang W, 2005). In addition to these conventional therapies, traditional medicine also offers a number of plant-based treatments. In Benin, among the many medicinal plants used, *Moringa oleifera* stands out for its therapeutic effects in the symptomatic treatment of gonalgia (Agoyi E, 2014). However, its effectiveness in gonarthrosis has not yet been formally proven. Thus, this work brings the results of a clinical study that evaluated the efficacy of *Moringa oleifera* root powder applied as a poultice to the knee in the symptomatic treatment of gonarthrosis.

## Patients and Methods

### Study framework

The preparation of *Moringa oleifera* root powder, placebo, their packaging and labeling, and storage were carried out at the Institute of Applied Biomedical Sciences of the Faculty of Health Sciences of Cotonou in 2019. The clinical trial took place in the University Clinic of Rheumatology of the Hubert Koutoukou Maga University Hospital Center of Cotonou in 2019.

## Study type

This was a randomized, double-blind, placebo-controlled, open-label study to assess the efficacy of *Moringa oleifera* root powder used as a poultice in the symptomatic treatment of gonarthrosis. At the baseline visit, eligible patients who agreed to randomization were randomized to receive either placebo or *Moringa oleifera* root powder:

- **Group 1:** receiving a knee poultice of 30g of *Moringa oleifera* root powder once a day combined with Paracetamol 1g morning and evening for three consecutive days. The poultices must be kept for at least 12 hours.
- **Group 2:** receiving a knee poultice of 30g of placebo powder once a day combined with paracetamol 1g morning and evening for three consecutive days. The poultices must be kept for at least 12 hours.
- **Group 3:** Patients receive standard drug therapy consisting of a tier 2 analgesic (tramadol 150 mg daily for 15 days), a non-steroidal anti-inflammatory (diclofenac 150 mg daily for 15 days) and 2 triamcinolone infiltrations at 40mg (15 days apart). The patients in this group and the researcher are aware of the drug treatment.

## Inclusion, exclusion and non-inclusion criteria.

### Inclusion criteria

Patients were included in the study according to the following criteria:

- ✓ Have a diagnosis of retained gonarthrosis based on ACR criteria;
- ✓ Be in osteoarthritis flare at the start of the study;
- ✓ To be naïve to any analgesic or anti-inflammatory drug treatment at least one week before the start of the study;
- ✓ Have given written consent to the study.

### Non-inclusion criteria

- ✓ Patients with a chronic pathology and long-term treatment containing anti-inflammatory and/or analgesic drugs;
- ✓ Patients with motor deficits and/or impaired upper functions; patients with a history of gastric pathology;
- ✓ Patients having received infiltration or visco-supplementation less than six months prior to the study entry date;
- ✓ Patients with concomitant pain or a history of knee surgery that could disrupt or interfere with efficacy assessment;
- ✓ Pregnant and breastfeeding women were not included in the study.

### Exclusion criteria

Patients who did not receive all three doses of Placebo or Moringa on three consecutive days, patients who were noncompliant with drug treatment over the 15 days of treatment, and patients who were lost to follow-up were excluded from the study.

### **Frequency and duration of monitoring.**

Patients underwent a clinical examination (knee examination) in hospital or at home for those who could not move about, at Day(D)0, D3, D7, D15, D30, D45, D60, D90. This examination enabled pain to be assessed using the visual analog scale (VAS) and Lequesne index at D0, D3, D7, D15, D30, D45, D60 and D90. When pain reappeared in a patient with an intensity greater than or equal to the initial at VAS, the patient was withdrawn from the study and referred to his rheumatologist for management.

### **Criteria for assessing the efficacy of *Moringa oleifera*.**

#### ***Primary efficacy endpoint for Moringa oleifera root powder***

The primary endpoint was therefore the evaluation of effect size ( $g^*$ ) for VAS at D3, D15, D30, D60, D90. Application of the *Moringa oleifera* poultice was considered very effective if  $g^* \geq 0.8$ ; moderately effective if  $g^* \in [0.5; 0.8[$  and not very effective if  $g^* \in [0.2; 0.5[$ .

#### ***Secondary efficacy criteria for Moringa oleifera***

##### **Lequesne index**

The first secondary endpoint was the evaluation of effect size for Lequesne index (LI) at D3, D15, D30, D60, D90. Application of the *Moringa oleifera* poultice was considered very effective if  $g^* \geq 0.8$ ; moderately effective if  $g^* \in [0.5; 0.8[$  and not very effective if  $g^* \in [0.2; 0.5[$ .

##### **Duration of recurrence of gonalgia after discontinuation of treatment**

The second secondary endpoint was the mean duration of pain recurrence. The efficacy of the *Moringa oleifera* arm was demonstrated if the mean duration of pain recurrence after treatment discontinuation was greater than that of the placebo arm.

### **Data processing and statistical analysis**

Data were entered using Epi info software version 7.2.1.0. We calculated an effect size at D3, D15, D30, D60, D90 using the Hedges statistic corrected for small samples as follows:

$$\text{Hedges' } g = \frac{\frac{m_1 - m_2}{sd^*_{\text{pooled}}}}{\frac{m_1 - m_2}{sd^*_{\text{pooled}}}}$$

$$Sd^*_{\text{pooled}} = \sqrt{\frac{(n_1 - 1)SD_1^2 + (n_2 - 1)SD_2^2}{(n_1 + n_2) - 2}} \sqrt{\frac{(n_1 - 1)SD_1^2 + (n_2 - 1)SD_2^2}{(n_1 + n_2) - 2}}$$

$$\text{Hedges' } g^* \text{ corrected} = g \left( 1 - \frac{3}{4(n_1 + n_2) - 9} \right) \left( 1 - \frac{3}{4(n_1 + n_2) - 9} \right)$$

m1 and m2: Average at a given time, SD: standard deviation of a group, SD\*pooled: weighted and pooled standard deviation, n1 and n2 group sizes. Throughout the study, “positive g” favours Moringa and “negative g” favours Placebo or drug treatment. The Hedges’ g values were 0.2 as small, 0.5 as medium, and 0.8 as large. Student's superiority of means test was also used to assess the difference between the different groups. This difference is statistically significant if  $p < 0.05$ .

### **Ethical considerations:**

#### **Ethical Committee**

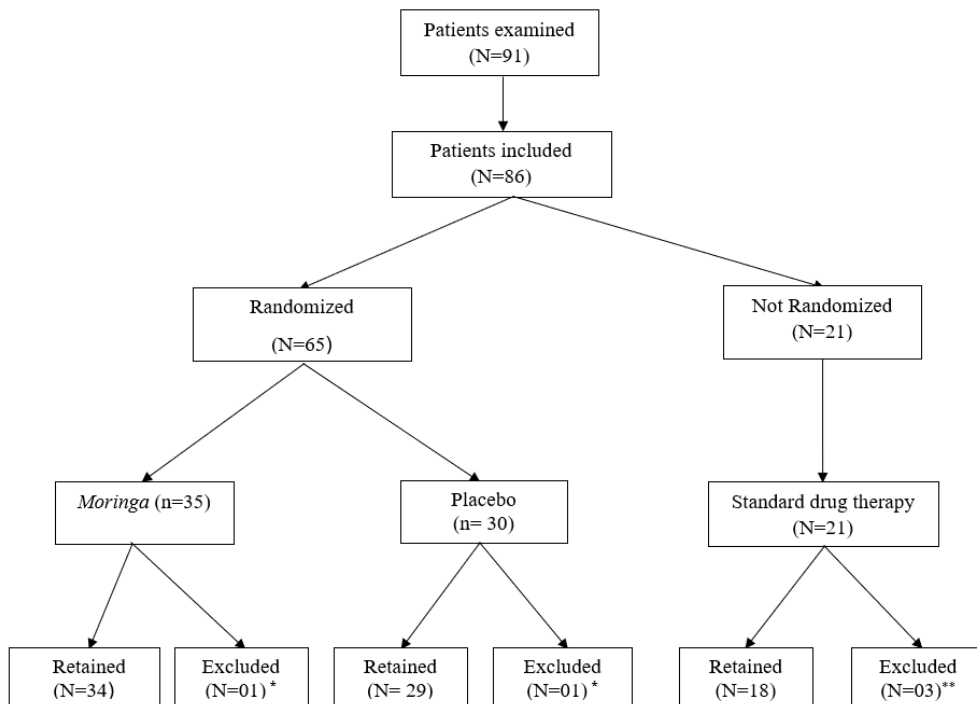
The present study was submitted for approval to the Ethics Committee of the Cotonou Faculty of Health Sciences, which gave its favorable opinion No. 002-20/UAC/FSS/CER-SS.

#### **Information and consent**

All patients were informed that participation in the study was completely voluntary, and that they could withdraw at any time. They signed the consent form after reading and explaining its contents.

### **Results**

Ninety-one (91) patients were examined, of whom eighty-six (86) were included in the study. Of the 86 patients included, 65 were randomized and 21 non-randomized. The 65 randomized patients were divided into two groups: the Moringa group, comprising 35 patients; and the placebo group, comprising 30 patients. 01 patient in each group was excluded. Thus, 34 patients completed the study in the Moringa group and 29 in the placebo group. The 21 non-randomized patients received drug treatment. 03 patients were lost to follow-up, and 18 patients in this group completed the study. Of the 86 patients included, 81 completed the study (94.18%) as shown in Figure 1.

**Figure 1:** Distribution of patients according to their group

\*Patient who did not receive all three doses of Placebo, *Moringa oleifera* root powder on three consecutive days.

\*\*Patients lost to follow-up.

The study population was characterized by a female predominance of 92%, with a mean age of 57.94 years, ranging from 34 to 85 years. Grade I obesity was found in most patients. Clinically, the average intensity of knee pain at the beginning of the study was 7.31, with extremes ranging from 3 to 10. The average functional impact of gonarthrosis on daily life at the start of the study was 14.73, with extremes from 8 to 23. The majority of patients had presented with tricompartmental, bilateral gonarthrosis of Grade III (Table 1).

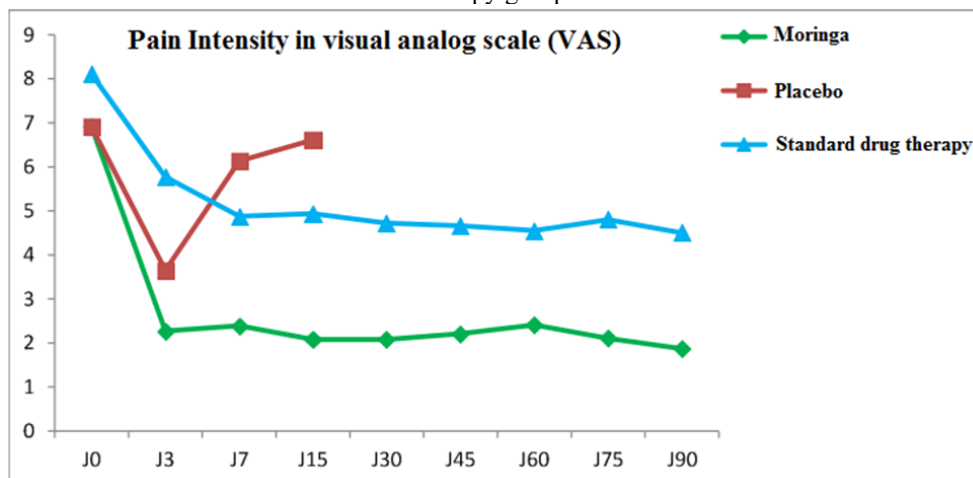
**Table 1:** Sociodemographic, clinical and paraclinical characteristics of patients

| Characteristics       |         | Moringa            | Placebo            | Standard drug therapy |
|-----------------------|---------|--------------------|--------------------|-----------------------|
| Sex                   | Male    | 02 (5,88%)         | 4 (13,86%)         | 00 (00%)              |
|                       | Female  | 32 (94,12%)        | 25 (86,21%)        | 18 (100%)             |
| Age (years)           |         | <b>58,02±1,02</b>  | <b>58,10±1,01</b>  | <b>57,70±0,89</b>     |
| Body mass index       |         | 34,21±2,3          | 32,08±1,8          | 28,72±1,8             |
| Pain intensity in VAS | < 5     | 01 (2,94%)         | 03 (10,44%)        | 00 (00%)              |
|                       | ≥ 5     | 33 (97,05%)        | 26 (89,65%)        | 18 (100%)             |
|                       | Average | <b>6,91 ± 0,34</b> | <b>6,91 ± 0,60</b> | <b>8,11 ± 1,02</b>    |
| Lequesne index        | < 10    | 01 (2,94%)         | 01 (3,44%)         | 00 (00%)              |

|                              |                               |                                   |                                   |                                  |
|------------------------------|-------------------------------|-----------------------------------|-----------------------------------|----------------------------------|
|                              | ≥ 10<br>Average               | 33 (97,05%)<br><b>14,57± 1,28</b> | 28 (96,56%)<br><b>14,10± 1,23</b> | 18 (100%)<br><b>15,54± 2 ,03</b> |
| <b>Seat of gonarthrosis</b>  | Tricompartmental gonarthrosis | 24 (70,58%)                       | 26 (89,65%)                       | 18 (100%)                        |
|                              | Femorotibial gonarthrosis     | 10 (29,41%)                       | 03 (10,34%)                       | 00 (00%)                         |
| <b>Grade of gonarthrosis</b> | II                            | 07 (20,59%)                       | 04 (13,79%)                       | 00 (00%)                         |
|                              | III                           | 23 (67,65%)                       | 18 (62,07%)                       | 14 (77,77%)                      |
|                              | IV                            | 04 (11,76%)                       | 07 (24,14%)                       | 04 (22,22%)                      |

The standardized effect size calculation for pain intensity for the Moringa and Placebo groups was 1.07 (95% CI [1.02; 2.10]) and 3.10 (95% CI [2.92; 3.11]) at D15 with  $p= 0.00000$ . As follow-up of Placebo patients was stopped at D15, the effect size for pain intensity could not be calculated beyond D15. Similarly, the effect size for pain intensity in the Moringa and drug treatment groups was 2.82 (95% CI [2.28; 3.4]) at D3; 2.48 (95% CI [1.95 ; 3.12]) at D15; 1.39 (95% CI [1.22; 1.78]) at D30; 1.43 (95% CI [1.36; 2.08]) at D60; 1.68 (95% CI [1.42; 1.90]) at D90 ( $p= 0.0001$ ). These different values suggest a superiority of Moringa over Placebo and drug treatment in terms of pain reduction. Thus, in terms of pain intensity assessed by VAS, Moringa-based treatment proved more effective than Placebo and drug treatment, with a significant clinical improvement and a statistically significant difference over a period of more than 03 months, as shown in figure 2.

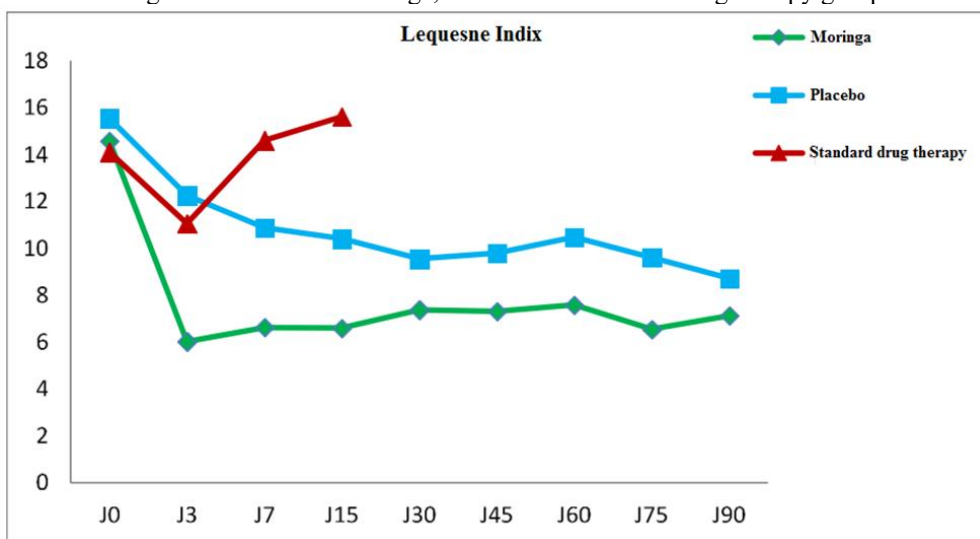
**Figure 2:** Evolution of patients' pain intensity in the Moringa, placebo and standard drug therapy groups



Standardized effect size calculations for LI at D3 and D15 were 1.75 (95% CI [1.26; 1.96]) and 2.98 (95% CI [2.28; 4.30]) respectively in the Moringa and Placebo groups, with  $p= 0.0001$ . As follow-up of Placebo

patients was stopped at d15, the effect size for LI could not be calculated beyond D15. Similarly, the effect size for LI in the Moringa and drug treatment groups was 2.23 (95% CI [2.02; 3.1]) at D3; 1.35 (95% CI [1.33 ; 2.08]) at D15; 1.97 (95% CI [0.75; 1.99]) at D30; 1.13 (95% CI [1.09; 1.96]) at D60 and 0.55 (95% CI [0.46; 1.08]) at D90 ( $p < 0.0001$ ). These values demonstrate the superiority of Moringa over Placebo and drug treatment for IL. Thus, in terms of improvement in the functional index assessed by the LI, Moringa-based treatment proved more effective than placebo and drug treatment, with significant clinical improvement and a statistically significant difference over a period of more than 03 months, as illustrated in figure 3.

**Figure 3:** Evolution of functional impotence and patient autonomy in activities of daily living over time in the Moringa, Placebo and standard drug therapy groups



## Discussion

The clinical characteristics of the studied patients were typically those of a population with knee osteoarthritis (Zhang W, 2005). The severity of arthritic pain and functional disability were significant at the beginning of the study.

The results of the effect size calculation for pain intensity and LI showed a standardized difference greater than 0.8 in the Moringa and placebo groups over a duration of 2 weeks ( $p < 0.0001$ ) on one hand, and in the Moringa and medication treatment groups over a duration of 3 months ( $p < 0.0001$ ) on the other hand. Thus, patients treated with the *Moringa oleifera* poultice experienced significantly greater clinical improvements compared to patients treated with the placebo and those who received medication treatment. This clinical improvement became significant as early as the 3rd day and continued throughout the follow-up period. The efficacy of the



Moringa-based poultice compared to the placebo can be easily explained by its chemical composition, which has revealed the presence of several molecular families, most of which have anti-inflammatory and analgesic properties (Kasolo JN, 2011). This anti-inflammatory property of *Moringa oleifera* root extracts was demonstrated orally in the works of Caceres et al. in 1992 and Tall in 2000. The superiority of the efficacy of the Moringa-based poultice over medication treatment would be due to the mechanisms of action of the various molecules contained in the hydroethanolic extract. First, according to Tabart in 2004, flavonoids possess anti-inflammatory activity by inhibiting the expression of pro-inflammatory genes, pro-inflammatory molecules (cytokines), PLA2, COX, LOX, INOS, and myeloperoxidases (Tabart J, 2011; Martini MC, 2003). Therefore, flavonoids exert an inhibitory action on the entire catabolic reaction of osteoarthritis by decreasing not only the synthesis but also the biological effect of chondrolytic chemical substances. Then, Mota et al (2001) showed that tannins exert acute and chronic anti-inflammatory activity by reducing the vascular permeability of the postcapillary venules in the synovial membrane, thus preventing the migration of neutrophils and macrophages. Therefore, the poultice made from *Moringa oleifera* roots would have an inhibitory effect on all phases of the inflammatory reaction, unlike NSAIDs, which are only COX inhibitors (Betina-Bencharif R, 2014). Finally, the superiority of the efficacy of the Moringa-based poultice over medication treatment could also be explained by a synergy of the simultaneous effects of several molecules with anti-inflammatory properties, such as flavonoids (Tabart J, 2011; Martini MC, 2003), coumarins (Fleurentin J, 1990) tannins (Mota S, 1985) saponins (Betina-Bencharif R, 2014) and analgesics like alkaloids (Badiaga M, 2011). However, experimental studies are necessary to confirm the mechanisms of action of the different molecules present in the powder of *Moringa oleifera* roots.

Other plants can be used to relieve joint pain. Some have been the subject of clinical studies, and their effectiveness is recognized by various organizations such as the WHO, EMA, and ESCOP (Bourgeois L, 2016). Indeed, the work of Schmid et al. demonstrated the effectiveness of the bark of *Salix alba* (white willow) in the symptomatic treatment of gonarthrosis compared to placebo. A significant clinical improvement was observed from 240 mg of willow bark extract (salicin) taken once daily orally after 15 days of treatment (Schmid B, 2001). The efficacy of willow branch bark is due to the anti-inflammatory properties related to the salicylic derivatives it contains. Willow bark extract is a COX inhibitor (Bourgeois L, 2016). However, willow branch bark is less effective than NSAIDs, which justifies its use only as a traditional remedy validated by the EMA for this indication. Similarly, several researchers have studied the therapeutic effects of the root

of *Harpagophytum procumbens* on arthritic pain. It has been found to reduce mild to moderate pain and functional disability after 12 weeks of treatment with a dosage of 2400 mg of *Harpagophytum* root extract per day taken orally, according to the work of Wegener et al. in 2003 (Bourgeois L, 2016, Wegener T, 2003). Its effectiveness in treating osteoarthritis depends on its chemical composition rich in harpagoside, which gives the roots anti-inflammatory properties. The extract of *Harpagophytum* roots would inhibit the synthesis of eicosanoids (Bourgeois L, 2016). According to Frerick et al., extracts of *Harpagophytum* could be used as a complementary treatment to NSAIDs (Frerick H, 2021). These plants are all effective in the symptomatic treatment of gonarthrosis, but the roots of *Moringa oleifera* seem to stand out due to their mechanism of action, their superior efficacy compared to drug treatment, their very short onset time (3 days), and their very long duration of action (on average 2 months), despite being applied topically.

The average and maximum durations of knee pain recurrence after stopping treatment seem to support the superiority of the efficacy of *Moringa*-based treatment compared to placebo and medication treatment. The origin of the long-lasting action of *Moringa oleifera* roots could not be determined in our study, so we put forward the following hypotheses in an attempt to explain it:

- **Reservoir effect:** The long-lasting action of extracts from *Moringa oleifera* roots would be due to the accumulation of the active ingredient in the stratum corneum during the three days of treatment, followed by a gradual release over several months.
- **A long half-life:** The long duration of action of *Moringa oleifera* roots may be due to the long half-life of the active ingredient in the joint cavity.

This study also identified adverse effects of the poultice made from *Moringa oleifera*, primarily skin-related, such as itching, which are less significant compared to the adverse effects of NSAIDs and intra-auricular corticosteroids.

This study has limitations. Our small sample size does not allow us to establish the therapeutic efficacy of *Moringa oleifera* powder, nor its adverse effect profile. However, it did highlight a presumption of efficacy which can support the realization of more rigorous and extensive clinical studies.

## Conclusion

This study showed the therapeutic interest of *Moringa oleifera* roots in managing flare-ups of gonarthrosis. A poultice made from *Moringa oleifera* roots could represent a potential therapeutic alternative to medication due to its effectiveness, route of administration, dosage, and

fewer side effects. It is also useful to determine in future studies whether the co-administration of Moringa and medication would be an alternative to surgical treatment indicated in the terminal stage of gonarthrosis.

### Authors' contributions

Vigniako Roussaint DOSSOU-YOVO, Hilaire DOSSOU-YOVO and Abdou Razack OSSENI contributed to the conception and drafting of the study, Vigniako Roussaint DOSSOU-YOVO, Hilaire DOSSOU-YOVO and Xavier Cossi ZOMALHETO contributed to Recruitment, randomization, treatment administration and patient monitoring, Vigniako Roussaint DOSSOU-YOVO, Abdou Razack and OSSENI Anatole LALEYE contributed to Production of placebo and Moringa oleifera poder.

**Conflict of Interest:** The authors reported no conflict of interest.

**Data Availability:** All data are included in the content of the paper.

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