ORIGINAL ARTICLE

The Efficacy of I-ALP Analgesic Gel in Acute and Subacute Musculoskeletal Pain: A Randomized Double-Blind Controlled Trial

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Objective: To study the efficacy of Immortelle extracts, Arnica, Longan seed, Plai (I-ALP) analgesic gel in acute and subacute musculoskeletal pain.

Materials and Methods: The present study was conducted at the Rehabilitation Center of a tertiary referral hospital. A novel herbal gel consisting of Plai, Longan seed, Arnica, and Immortelle extracts was developed. One hundred four patients with acute and subacute musculoskeletal pain, with a numerical rating scale (NRS) of 3 or less, were randomized to two equal groups with the treatment group and control group, both having 60 patients each. The treatment group received I-ALP analgesic gel with rehabilitation and a physical therapy program while the control group received placebo gel with rehabilitation and a physical therapy program. Both groups were instructed to apply analgesic gel in the painful area twice a day, in combination with the rehabilitation and physical therapy program, three times a week for two weeks. Both groups were assessed for NRS score, active range of motion, and quality of life in pretest, during the test at one week, and post-test at two weeks.

Results: Ninety-five patients completed the experimental study, with 50 in the intervention group and 45 in the placebo group. Four herbal extracts, including Plai extract 14%, Longan seed extract 8%, Arnica extract 5%, and Immortelle extract 4%, were developed as the I-ALP analgesic gel. The present study found that the treatment group had significant reduction in pain response rate ($p<0.05$). Within one week, 26% of the treatment group had a reduction of NRS scores of 50%. At post two weeks, 88% of the treatment group had reduction of NRS scores of 50%. The number of patients in the treatment group who had reduced pain response rate was up to 3.67 times greater than in the control group (95% confidence interval 1.33 to 11.28). There was no significant difference in quality-of-life scores between the two groups.

Conclusion: The I-ALP analgesic gel effectively reduces pain in patients with musculoskeletal pain in acute and subacute phases.

Keywords: Acute pain; Subacute pain; Musculoskeletal pain; I-ALP; Analgesic gel

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Acute or sub-acute musculoskeletal pain can result from overexertion of muscle or in cases where muscle has not been used regularly. When the muscle is injured, symptoms including soreness and pain are often present. In addition, there could be pain at the local point of injury, extreme tenderness at the active trigger point/referred point, and tightness in the muscles, which can affect movement of the joints[1]. Muscle pain is a widespread problem that can occur to anyone. In 2002, it was reported that 14.9% of the population suffered from pain of which 65.4% was classified as muscle pain[2].

Current treatment methodology for patients with muscle pain preferred by most physicians includes the combination of pharmacologic treatment and physical therapy. Two groups of drugs are usually considered, non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol. NSAIDs are the most effective drugs that can be used to reduce the symptoms of muscle injury or pain. However, there are certain side effects such as gastrointestinal bleeding, stomach ulcers, perforation of the stomach as well as increased risk of myocardial infarction and cerebrovascular disease. Paracetamol is widely used but has lower efficacy in reducing muscle pain[3,4]. Furthermore, it has certain side effects such as gastrointestinal bleeding, stomach ulcers, perforation of the stomach as well as increased risk of myocardial infarction and cerebrovascular disease.

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There is a current lack of data on efficacy of herbal medicines and their role on musculoskeletal pain management. Due to this, there is a need to examine the benefit of herbal medicines for muscular soreness and pain treatment. The authors' institution is interested in developing a novel topical pain relief made from herbal extractions that is able to reduce swelling, inflammation, and muscle pain with the goal to help lower the amount of NSAID use among patients. Although often used, there is a lack of high-quality trials studying the efficacy of herbal medicines on acute and subacute musculoskeletal pain.

Therefore, the purposes of the current study were to[5] determine efficacy of a novel herbal topical medicine in reducing pain in acute and subacute muscular pain, as well as, determine any differences in range of motion and quality of life between the treatment versus control group.

Materials and Methods

The present study was done in two phases as follows:

Phase 1: Literature review on the development of Immortelle extracts, Arnica, Longan seed, Plai (I-ALP) analgesic gel formula. This was done by contracting the partner of Bangkok Dusit Medical Service Public Company Limited (BDMS). The gel contains four herbal components including 14% Plai extract, 8% Longan seed extract, 4% Arnica extract, and 4% Immortelle extract. The proportion of each component was formulated in the right concentration for pre-clinical and clinical trials and found to be safe for clinical practices.

In acute and subacute muscular pain patients[6], it was found that Arnica extract, which is a traditional herb derived from Europe has an indication to reduce muscle pain, joint pain, and related disorders. From previous studies, research in both pre-clinical and clinical study suggested that Arnica with 5% dosage showed statistical significance in anti-inflammatory effects. Immortelle extract from Immortelle is a plant of the family *Helichrysum italicum*, a medicinal herb for pain relief and anti-inflammatory effect. It was found that the extract from Immortelle at 4% dosage is safe and effective in reducing inflammation[7-9]. Phial is an herb found in Thailand and has properties in reducing bruises and sprains. It was evident that the use of Phial cream with 14% concentration for seven days showed significant effect in reducing muscle pain after exercise compared to the 7% concentration or placebo[10]. Additionally, according to previous studies, Longan seed extract has been shown to have anti-inflammatory effects[11].

Phase 2: Research to determine the effectiveness of I-ALP analgesic gel. The current study used a randomized controlled trial in a two-way blind method. Ninety-nine subjects who passed the inclusion criteria used for the present study were patients suffering from acute and subacute muscular pain and received treatment at the Rehabilitation Center Bangkok Hospital between January 2020 and April 2021. The present research has been certified by the Institutional Review Board (IRB) at Hospital Headquarters, Project Code COA 2020-18, and all participants were provided with information about the study and given their consent to participate in the study.

Sample size

The sample size of the present research was calculated based on the two-sample parallel design for binary data. The key assumption was that there would be reduced pain among those who received I-ALP treatment when compared to the placebo group by at least 10%. The proportion of placebo must have 40% to 50% success rate while the experimental group who received I-ALP pain reliever gel had at least 60% success rate treatment of myalgia with type 1 error (α)=5% and type 2 error (β)=0.2 or equal to the test power of 80%. Hence, 98 suitable samples were obtained to prevent sample loss during the experiment. The authors increased the sample size by 20% of the calculated amount to account for attrition. Therefore, 120 subjects were included in the present study.

Random allocation method

The present study was a randomized controlled trial, evaluating potency of I-ALP analgesic gel, the participant allocation was meticulously executed in three critical steps to ensure blinding and integrity. Initially, 120 random sequences were generated using Stata Statistical Software, version 15 (StataCorp LLC, College Station, TX, USA), employing a block randomization method with blocks of four, a process overseen by an independent investigator at the BDMS Research Center. These sequences were then securely transmitted to a pharmaceutical manufacturing plant, where the I-ALP analgesic gel and its placebo counterpart were packaged in strict accordance with the random list, ensuring indistinguishable packaging to maintain the double-blind study design. Finally, these packages, labeled

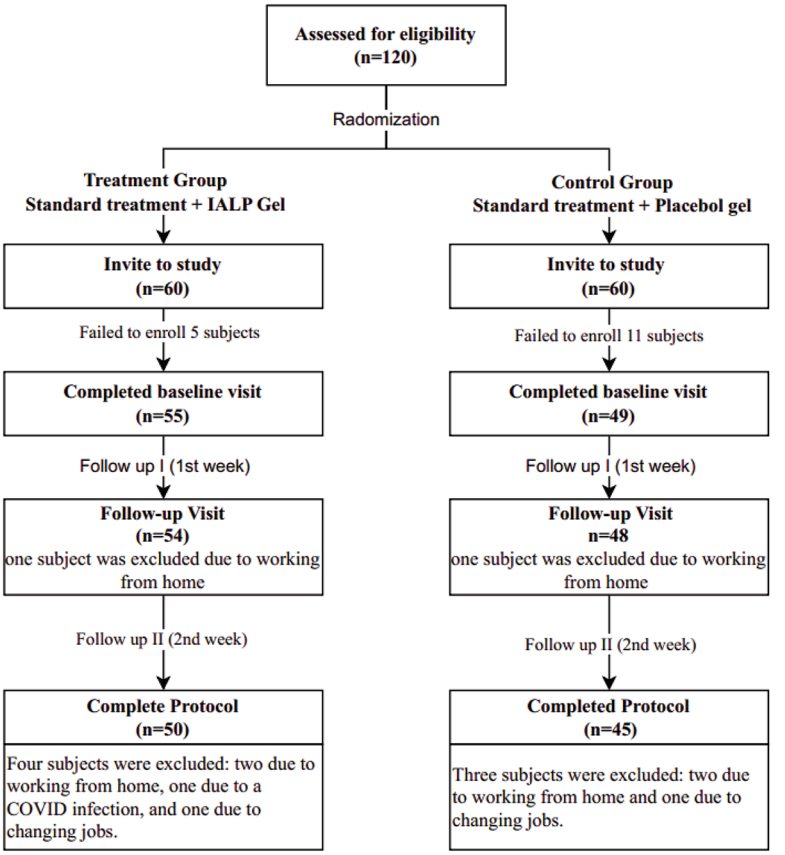

Figure 1. Flowchart of the clinical study invitation.

only with sequence numbers, were delivered to the hospital's medicine warehouse, keeping the treatment identity concealed from everyone involved in the trial, including physicians, physical therapists, pharmacists, patients, and outcome assessors, thereby preserving the trial's methodological rigor and validity.

Inclusion criteria

Inclusion criteria were as follow:

1) Aged over 20-year-old

2) Diagnosed by physicians with acute or subacute muscular pain and had the pain symptoms for three months from the causes derived from:

2.1) Muscle strain from activities

2.2) Muscle soreness after exercise or physical activities

2.3) Muscular pain in the neck and shoulders that were associated with office syndrome or work-related activities

3) The pain score during rest ranged from 1 to 3 based on numeric pain rating scale.

4) Fluent in Thai

Exclusion criteria

Exclusion criteria were as follow:

1) Patients who used NSAID or other topical pain treatment seven days prior to participation.

2) Allergy to massage oil and ingredients of Plai extract, Arnica extract, Immortelle extract, and Longan seed extract.

3) Pregnancy

Intervention

One hundred twenty subjects were enrolled in the present study (Figure 1). Ninety-nine patients met the inclusion criteria and were able to participate in the study. All subjects who participated were assessed by rehabilitation physicians to identify the type of muscle pain such as at rest, work related, and exercise. The physicians examined the patients using ergonomics assessment and provided the diagnosis as well as analyzed the cause of pain[12].

Subjects consented and randomly assigned to the experimental group were given I-ALP analgesic pain in combination with the rehabilitation program and postural physiotherapy which involved hot

Table 1. General background information of subjects

Variable	Total (n=95)	Treatment (n=50)	Control (n=45)	p-value
Sex; n (%)				0.177
Male	15 (15.8)	5 (10.0)	10 (22.2)	
Female	80 (84.2)	45 (90.0)	35 (77.8)	
Age (years); mean [SD]	32.4 [8.01]	33.1 [8.70]	31.6 [7.18]	0.373
BMI (kg/m^2); n (%)				0.864
Underweight (<18.5)	9 (9.5)	5 (10.0)	4 (8.9)	
Normal (18.5 to <25)	65 (68.4)	33 (66.0)	32 (71.1)	
Overweight (≥25)	21 (22.1)	12 (24.0)	9 (20.0)	
NRS; mean [SD]	2.85 [0.356]	2.90 [0.303]	2.80 [0.405]	0.18
EuroQOL; mean [SD]	76.8 [8.98]	76.4 [10.7]	77.2 [6.73]	0.634

BMI=body mass index; NRS=numeric pain rating scale; SD=standard deviation

compression and stretching regime to relieve the muscle pain. For the control group, subjects were given a placebo topical cream along with the programs as given to the experimental group.

Both groups received the same standard application guidelines for the topical gels. All subjects were required to apply the topical cream to the pain area twice a day, morning, and evening for two weeks and underwent physical therapy three times a week for two weeks. Patients were advised to use paracetamol tablets if the pain increased.

Outcome measurement

Two groups of subjects were assessed on:

1) Self-assessment using numeric pain rating scale (NRS)

2) Assessment of the range of motion from goniometer instrument

3) Quality of life assessment using EuroQOL

The assessment was conducted by rehabilitation therapists at the given period prior to the experiment, during the experiment at week 1, and post the experiment at week 2. Qualitative research methodology was used to evaluate the satisfaction rate for the effectiveness of the treatment in reducing muscle pain.

Statistical analysis

1) Descriptive statistics were used to analyze the general background data of the samples, with results presented using percentages, means, and standard deviations.

2) The comparison of pain scores between the experimental group and the control group was conducted during the trial at week 1 and after the trial at week 2, using chi-square and logistic regression for statistical analysis. Covariate variables, such as pre-participation pain level, gender, age, and pain location, were controlled. The results were presented as the success rate of pain reduction, quantified as a 50% decrease in pain. Additionally, the effectiveness of I-ALP treatment on cervical spine and shoulder movements was analyzed using repeated measures ANOVA. Data analysis was performed using Stata Statistical Software, version 15 (StataCorp LLC, College Station, TX, USA).

Results

The result from phase one illustrated that the appropriate formulation of I-ALP analgesic gel should contain four herbs including 14% Plai extract, 8% Longan seed extract, 5% Arnica extract, and 4% Immortelle extract. The gel was clear in color with a pleasant aroma smell from the unique herbal extraction. When applied to the affected muscle pain area, the gel would slowly absorb into the skin providing a cool and relaxing sensation and no stickiness feeling. With the unique properties of four herbs combined, it created a synergistic effect in reducing swelling, inflammation, and pain. The gel could be kept for three years at room temperature.

The efficacy of I-ALP analgesic gel was tested in 104 subjects in accordance with the inclusion criteria, of which 52 subjects participated in the control group while another 52 subjects were in the experimental group. Overall, only nine patients were lost to follow-up, with two in the experimental group and seven in the control group. Due to this, 95 subjects were used in collecting data and conducting further analysis.

The analysis of general demographic and baseline data in the groups is shown in Table 1. There were 95 subjects, classified into 15.8% males and 84.2% females. The average age of the participants was 32.4 years old and 9.5% of the total subjects

Table 2. Comparison of pain score between the experimental group and the control group during the study (week 1) and post-study (week 2)

Visit	Total (n=95); n (%)	Treatment (n=50); n (%)	Control (n=45); n (%)	Odds ratio (95% CI)	p-value
1st week					
Decrease <50%	67 (70.5)	37 (74.0)	30 (66.7)	Reference	
Decrease ≥50%	28 (29.5)	13 (26.0)	15 (33.3)	0.7 (0.29 to 1.7)	0.4347
2nd week					
Decrease <50%	21 (22.1)	6 (12.0)	15 (33.3)	Reference	
Decrease ≥50%	74 (77.9)	44 (88.0)	30 (66.7)	3.67 (1.33 to 11.28)	0.0157

CI=confidence interval

Table 3. The average increased EuroQQL score during the study (week 1) and post-study (week 2)

Visit	Total (n=95); mean (SD)	Treatment (n=50); mean (SD)	Control (n=45); mean (SD)	p-value
Baseline visit	76.8 (8.98)	76.4 (10.7)	77.2 (6.73)	0.634
1st week	81.6 (7.45)	81.6 (7.96)	81.7 (6.94)	0.921
2nd week	87.5 (7.02)	88.0 (6.93)	86.9 (7.16)	0.455

SD=standard deviation

had low body mass index (BMI), 68.4% had normal BMI, and 22.1% had high BMI. It was also noted that there was no difference in the basic characteristics of both groups. The pre-test data analysis indicated no significant differences between the groups in terms of general background characteristics. Furthermore, the pre-test phase analysis revealed that both groups exhibited comparable pain levels (p=0.18) and quality of life scores (p=0.634).

Referring to Table 2, in the first week of the study, the level of pain was reduced by 50% in 13 subjects in the experimental group (26%), while in the control group, 15 subjects (33.33%) had reduction in the pain level. During the second week, 44 subjects (88%) had 50% reduction in pain level, while only 30 subjects (66.7%) in the control group scored lower pain levels. This indicated that more than half of the experimental group subjects had reduced more than half of their pain level scores when compared to the control group. The experimental group had a 3.67 times higher rate of success in terms of reducing their pain level and 95% confidence level score at 1.33 to 11.28.

The analysis of EuroQOL scores showed increased scores in both groups between week 1 and week 2 (Table 3). For week 1, the average was higher in both groups but showed no difference between groups with EuroQOL at the first week for the treatment group at 81.6 (7.96) and the control group at 81.7 (6.94), p=0.921). In week 2, the average score was also higher in both groups showing no significant differences between groups with EuroQOL at the second week for the treatment group was 88.0 (6.93) while the control group was 86.9 (7.16), p=0.455).

There was also qualitative data to complement the current study's results for the two-week phase. It was found that patients who received the I-ALP analgesic gel felt more relaxed from the aromatic scent and the cool sensations, while the subject who received placebo treatment felt no difference when applying the gel.

Intention-to-treat analysis and pain score reductions between treatment and control groups were compared across two time points, during the trial at week 1 and post-trial at week 2, controlling for covariates such as pre-participation pain level, gender, age, and pain location (Table 4). In the first week, 25.8% of participants experienced a 50% or more pain reduction, with no significant difference between the treatment group at 23.3% and the control group at 28.3% (OR 0.77, 95% CI 0.34 to 1.75, p=0.5320). By the second week, the proportion of participants achieving this level of pain reduction was at 78.3%, with a higher, yet non-significant, success rate in the treatment group at 85.0% compared to the control at 71.7% (OR 2.24, 95% CI 0.92 to 5.74, p=0.0803). The trends suggested a potential benefit of the treatment, though statistical significance was not attained at the conventional 0.05 level during the observed periods.

Table 5 presents the effectiveness of treatment on cervical spine and shoulder movements at baseline, first week, and second week post-treatment for control and treatment groups. The p-values

Table 4. Intention-to-treat analysis of pain reduction in treatment and control groups during the study (week 1) and post-study (week 2)

Visit	Total (n=120); n (%)	Treatment (n=60); n (%)	Control (n=60); n (%)	Odds ratio (95% CI)	p-value
1st week					
Decrease <50%	89 (74.2)	46 (76.7)	43 (71.7)	Reference	
Decrease ≥50%	31 (25.8)	14 (23.3)	17 (28.3)	0.77 (0.34 to 1.75)	0.5320
2nd week					
Decrease <50%	26 (21.7)	9 (15.0)	17 (28.3)	Reference	
Decrease ≥50%	94 (78.3)	51 (85.0)	43 (71.7)	2.24 (0.92 to 5.74)	0.0803

CI=confidence interval

showed the statistical significance of changes over time and between groups.

Discussion

The current study demonstrated that this novel I-ALP analgesic gel formula containing herbs, including 14% Plai extract, 8% Longan seed extract, 5% Arnica extract, and 4% Immortelle extract, can reduce inflammation in patients with acute muscle pain and the sub-acute phase. The results were statistically significant when topical analgesic gel is used in conjunction with physical therapy. The results from this I-ALP analgesic gel efficacy test reflected that, even though physiotherapy therapy using hot compression along with paracetamol medication were given to both groups, subjects received the I-ALP analgesic gel had a better pain reduction than the placebo group. This may be due to the synergistic effect of the four ingredients from I-ALP analgesic gel and the aroma and cooling sensation in reducing muscle pain in both acute and subacute phases.

Previous studies in the pre-clinical phase using rat models suggested that Plai contained compound D or (E)-4-(3',4'-dimethoxyphenyl) but-3-en-2-ol, which has the ability to reduce inflammation in the acute phase of muscle pain as it inhibited rat paw edema by carrageenan. Additionally, it was also found that Plai also contains (E)-1-(3',4'-dimethoxyphenyl) butadiene (DMPBD), which can reduce edema.

A previous study conducted on patients with quadriceps pain characterized by delayed onset muscle soreness also showed reductions in pain in patients treated with Plai extract herbal gel. The authors categorized 75 patients into three groups, 1) receiving pain relief with 7% Plai concentration, 2) receiving 14% concentration, and 3) receiving placebo. Patients were required to apply the gel for eight hours each week. The results illustrated that at 14% concentration, the pain was significantly reduced among subjects who used the gel when compared to the placebo group[13].

Furthermore, the current study's results are consistent with a previous study on the anti-inflammatory effects of longan seed in a rat model. It was found that the water extract of longan pericarp in 100 to 400 mg/kg can inhibit the edema in rat paw and block the carcinogenic substance. In addition, the extract increased antioxidants including superoxide dismutase and glutathione peroxidase.

With regards to the Arnica extract, there are other research studies that supported the outcome of the current study. Arnica extract has been used to reduce the pain, particularly knee pain due to osteoarthritis. In a previous study, Arnica extract gel was given to a sample of 79 patients who suffered from knee pain. The patients applied topical medication for six weeks, twice a day. In the third and sixth week, the knee function improved. For Immortelle extract, there is limited information on the effectiveness of this type of herb in muscle pain. However, the efficacy of Immortelle extract, helichrysum oil demonstrated the ability to increase blood circulation, reduce swelling, and provide a pleasant smell for relaxation.

Regarding the quality-of-life scores of the experimental group and the control group after participating in the present study, it was found that the mean quality of life (EuroQOL score) increased in both groups but were not statistically different between the groups. This may be due to both groups receiving a standard physical therapy program, which included muscle stretching and the use of superficial heat in the treatment. This result is consistent with prior literature, which found that standard physical therapy programs could improve quality of life among patients with muscle pain.

Conclusion

The I-ALP gel is a topical analgesic formula

Table 5. Effectiveness of treatment on cervical spine and shoulder movements: repeated measures ANOVA results

Variable	Group	Time; mean (SD)			p-value	
		Baseline visit	1st week	2nd week	Time	Time*Group
Cervical spine						
Flexion	Control	34.0 (6.3)	37.9 (6.2)	40.5 (5.0)		
	Treatment	36.1 (7.2)	39.5 (5.8)	41.4 (4.0)	<0.0001	0.5718
Extension	Control	35.4 (7.5)	39.2 (8.1)	40.2 (7.2)		
	Treatment	36.3 (7.4)	39.9 (6.0)	42.1 (4.7)	<0.0001	0.4229
Right						
• Lateral flexion	Control	30.6 (7.2)	33.6 (5.7)	37.4 (6.7)		
	Treatment	32.2 (7.1)	35.2 (7.0)	37.8 (5.9)	<0.0001	0.5827
• Lateral rotation	Control	44.7 (9.7)	49.2 (8.4)	52.6 (7.6)		
	Treatment	44.4 (8.9)	48.2 (8.7)	52.7 (7.3)	<0.0001	0.6710
Left						
• Lateral flexion	Control	29.4 (6.6)	33.0 (7.5)	36.3 (7.6)		
	Treatment	31.3 (7.2)	33.0 (6.9)	36.3 (6.2)	<0.0001	0.1727
• Lateral rotation	Control	45.4 (9.5)	48.9 (8.8)	52.5 (7.7)		
	Treatment	43.6 (9.1)	47.4 (9.2)	51.2 (7.9)	<0.0001	0.9386
Shoulder						
Right						
• Flexion	Control	173.8 (9.6)	177.4 (6.6)	177.1 (15.3)		
	Treatment	173.9 (9.8)	178 (4.3)	179.6 (2.2)	<0.0001	0.4756
• Extension	Control	41.6 (5.7)	43.4 (5)	44.8 (3.4)		
	Treatment	42.2 (6.9)	43.5 (4.3)	43.5 (7.2)	0.0010	0.2790
• Abduction	Control	172.6 (12.8)	176.4 (8)	179.8 (1.6)		
	Treatment	173.1 (9.6)	177.6 (6.1)	179.4 (3.7)	<0.0001	0.6033
• Adduction	Control	42.2 (4.8)	43.8 (2.9)	44.9 (0.7)		
	Treatment	43.3 (2.8)	44.3 (1.7)	43.8 (6.4)	0.0065	0.1069
• Internal rotation	Control	65 (7.5)	67.8 (7.3)	69.2 (5.9)		
	Treatment	64.7 (7)	67.6 (5.4)	69.4 (3.4)	<0.0001	0.9010
• External rotation	Control	80.9 (10.5)	86.2 (6.7)	87.5 (8.4)		
	Treatment	81.2 (8.5)	86.6 (5.9)	87.1 (13.1)	<0.0001	0.9151
Left						
• Flexion	Control	172.3 (13.9)	177 (10.1)	179.5 (3.3)		
	Treatment	172.7 (12)	176.7 (6.7)	179.3 (3.2)	<0.0001	0.9250
• Extension	Control	41 (5.8)	43.4 (4.6)	44.7 (2.2)		
	Treatment	41.3 (4.8)	43.4 (4.3)	43.2 (7.5)	<0.0001	0.2429
• Abduction	Control	41.8 (5)	43.7 (2.9)	44.8 (1)		
	Treatment	42.1 (3.7)	44 (2.3)	43.8 (6.4)	<0.0001	0.4133
• Adduction	Control	170.6 (19.2)	175.9 (13.2)	179.8 (1.6)		
	Treatment	173.1 (10.9)	177.8 (5.2)	179.5 (2.7)	<0.0001	0.4195
• Internal rotation	Control	64.2 (7.9)	67.9 (7.5)	69.8 (4.8)		
	Treatment	63.8 (5.8)	66.3 (6.2)	68.7 (5.6)	<0.0001	0.6012
• External rotation	Control	78.7 (13.1)	85.8 (9.9)	87.9 (6.2)		
	Treatment	79.9 (9.4)	85.2 (8)	89 (3.4)	<0.0001	0.4801
Elbow						
Flexion	Control	145 (0)	145 (0)	145 (0)		
	Treatment	144.9 (1.6)	145.6 (5.9)	145 (0)	N/A	N/A
Extension	Control	0 (0)	0 (0)	0 (0)		
	Treatment	0 (0)	0 (0)	0 (0)	N/A	N/A
Supination	Control	85 (0)	85 (0)	85.1 (0.4)		
	Treatment	85 (0)	85 (0)	85 (0)	N/A	N/A
Pronation	Control	70 (0)	70 (0)	70 (0)		
	Treatment	69.5 (4.4)	70 (0)	70 (0)	N/A	N/A

SD=standard deviation

developed from four types of herbal components which include 14% Plai extract, 8% Longan seed extract, 5% Arnica extract, and 4%Immortelle extract. This novel topical gel can reduce inflammation of the muscles in patients with muscle pain in the acute and the semi-acute phase. When used in conjunction with physical therapy treatment for two weeks continuously, it is effective in reducing pain. Specifically, the current study found that 88% of patients who received I-ALP analgesic gel along with physical therapy experienced pain relief and the rate of pain reduction success was greater than the control group who was given the placebo treatment along with physical therapy by 3.67 times (95% confidence level 1.33 to 11.28). Therefore, it can be concluded that I-ALP analgesic gel can be used to reduce pain in patients with muscle pain in the acute and subacute phase effectively.

Safety

Throughout the study period, there were no incidences or serious adverse events. This is because the authors had strictly followed the inclusion criteria and excluded subjects with a history of allergic reaction to massage oils including Sunflower oil, and products containing Plai, Arnica extract, Immortelle extract, and Longan seed extract. This allowed the study to continue in a safe manner.

Implications for practice

The results showed that I-ALP analgesic gel was effective in reducing muscle pain in acute and subacute injuries. This implies that it can be used to treat pain from muscle injuries. I-ALP analgesic pain gel must be applied to the affected area at least twice a day continuously for two weeks.

Limitation

The present study was conducted in subjects with acute and subacute muscular pain. The findings have shown that I-ALP analgesic pain reliever gel can reduce muscle pain during this time period. However, the study also showed that pain persisted and did not improve among a proportion of subjects. This could be as a result of non-controlled factors such as lifestyle behaviors, office syndrome, and routine activities that continuously trigger pain. These factors reflect the limitations of the present research.

Suggestions for future research

The research on the efficacy of I-ALP analgesic gel should have expanded to more diverse groups such as athletes and people who experience muscle aches post exercise such as delayed muscle soreness.

What is already known on this topic?

There are many types of herbs that contain important compounds capable of reducing muscle pain. These herbs are popular and commonly used in tropical and other regions. Apart from using painkillers and anti-inflammatory medications, certain herbal remedies have natural properties to alleviate muscle pain and inflammation.

What does this study add?

The combination of tropical herbs such as Plai and Longan seed extracts along with herbs from the American region such as Anika and immortelle extracts can effectively reduce pain in patients experiencing musculoskeletal pain both acute and subacute phases, without causing any side effects.

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Authors' contributions

Roles and duties of the researchers and co-investigators in writing of the present research paper were the cooperation of the Rehabilitation Medicine Center led by PC with SJ as well as the Bangkok Health Research Center led by PK and TW. In addition, SJ from the Pharmacy Department, played a role in research design, research process, and the data collection process.

The data analysis was conducted by WC, and all the authors contributed to the composition, design, and comprehensibility of the present article.

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Conflicts of interest

The authors declare no potential conflicts of interest.

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