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Effectiveness of The Modified Formula of Ya-Tha-Pra-Sen on Relieving Neck and Shoulder Muscle Pain: Clinical Randomize Control Trail.

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Abstract

Ya-Tha-Pra-Sen (YTPS) has been utilized as a topical remedy to alleviate muscle pains since the Ayutthaya period. Formulated from a combination of 13 distinct herbs, YTPS offers a range of medicinal properties. This study aimed to develop an enhanced YTPS gel formula, referred to as YTPS-DG, by incorporating an additional 5 traditional Thai herbs. The efficacy of YTPS-DG in reducing muscle pains was then compared with the traditional YTPS formula. A randomized controlled trial was undertaken with 45 participants, aged 20 to 60. Participants were randomly assigned to one of three groups: the YTPS-DG group (modified formula), the YTPS-TG group (traditional formula), or the placebo group (PCBG). Each participant received gel samples packaged in 2.5 g units and was instructed to apply one package's worth to their upper trapezius muscle twice daily over a span of six days. Daily results were systematically documented in case record forms, and participants were monitored with follow-up checks every three days. Our findings revealed that YTPS-DG exhibited the most pronounced efficacy. There was a statistically significant reduction in pain from baseline for the YTPS-DG group ($P<0.05$) when compared to the YTPS-TG and placebo groups. Furthermore, YTPS-DG notably increased weight-bearing capacity (in kg) and enhanced the Range of Motion (ROM) in participants' neck and shoulder areas, as demonstrated by comparing results before and after application. In conclusion, the modified YTPS-DG formula proved to be superior in alleviating muscle pains and enhancing functional parameters compared to the traditional YTPS and placebo. Further studies are warranted to explore the underlying mechanisms and potential applications.

Keywords**:** *Pain relief gel; herbal extracts; Ya-Tha-Pra-Sen; reducing muscle pain; Thai traditional*

1. Introduction

Musculoskeletal disorders have been identified as one of the leading occupational and environmental health issues, affecting an estimated 167 individuals per 100,000 population in 2017 alone. Such disorders resulted in a substantial loss of work, with 6,642 recorded instances where employees required more than three days off, accounting for the highest percentage of total occupational hazards according to the disease situation report from the same year. These disorders, characterized by muscle pain and fibrosis, predominantly target the neck, shoulder, and upper back regions. Common treatment methodologies often involve self-medication with local treatments or conservative measures like massage, physical therapy, hot compress, and exercise (Sethpitak, 2515; Kingkaew, 2016; Zhou et al., 2022).

Historically, traditional medicinal practices have played a significant role in managing health conditions. Notably, during the Ayutthaya period, the Na-Rai traditional medicine textbook emerged as a systematic compilation of Thai pharmacological wisdom. One of the remedies documented in this text, referred to as "Ya-Tha-Pra-Sen," is of

particular interest. As the 58th entry in the Na-Rai traditional medicine textbook, the Ya-Tha-Pra-Sen formula was traditionally applied to areas of discomfort (Ministry of Public Health, n.d.). Its historical applications include the treatment of abnormal body strains, paralysis, angina, cramps, and muscle fatigue.

The formulation contains a mix of 13 herbs as documented in Table 1, which includes *Piper nigrum* L., *Alpinia galanga* (L.) Willd., *Boesenbergia rotunda* (L.) Mansf., and others. Key components of Ya-Tha-Pra-Sen such as Piper Nigrum, Allium Sativum, and Aloe Vera, are known to have specific therapeutic benefits (Ministry of Public Health, n.d.). Piper Nigrum, commonly referred to as Black Pepper, has an active compound known as piperine, known for its analgesic properties and potential anti-inflammatory and antioxidant effects. Allium Sativum, or Garlic, contains flavonoid compounds with antioxidant properties that can inhibit enzymes stimulating the production of inflammatory substances. Furthermore, Aloe Vera hosts several active compounds with robust anti-inflammatory properties that can alleviate inflammation and support skin health.

Recent studies investigating the herbal extracts from the Ya-Tha-Pra-Sen formula have shown that a specially developed Ya-Tha-Pra-Sen tincture exhibits anti-inflammatory, non-toxic, and antioxidant properties (Roiet et al., 2019). These findings highlight the therapeutic potential of this traditional formula, particularly when compared with placebo. Kanokkangsadal et al. (2020) further suggested its effectiveness in treating knee pain from osteoarthritis. Given the demonstrated anti-inflammatory, non-toxic, and antioxidant effects of the Ya-Tha-Pra-Sen tincture, it is evident that this traditional formula holds promise for potential therapeutic applications, particularly in the management of musculoskeletal disorders (Roiet et al., 2019). Additionally, Toelang et al. (2017) have explored different formulations of Ya-Tha-Pra-Sen, transitioning from tincture to gel.

However, limitations exist with the traditional Ya-Tha-Pra-Sen formula, as researched by Roiet et al. (2019). They discovered that Ya-Tha-Pra-Sen is primarily effective for relieving muscle pain, but it does not improve the range of motion (ROM) when evaluated based on within-group statistics. This suggests that the formula might benefit from more potent anti-inflammatory ingredients. Given this, there appears to be significant scope for enhancing the effectiveness of the Ya-Tha-Pra-Sen (YTPS) formulation through the addition of other medicinal herbs. Thus, this study aims to incorporate additional herbs that are recognized for their efficacy in traditional medicine globally. These herbs include *Sida acuta* Burm.f., *Cleome viscosa* L., *Dimocarpus longan* Lour., *Murraya paniculata* (L.) Jack, and *Acmella oleracea* (L.). The distinctive medicinal properties of these herbs are detailed in Table 2.

Table 1 Medicinal plants in Ya-Tha-Pra-Sen

Topicals medication	Scientific name	Thai common name	Use part
Traditional Ya-Tha-Pra-Sen (YTPS-TG)	*Piper nigrum* L.	Prik-Thai	Seed
	Alpinia galanga (L.) Willd.	Kha	Rhizoom
	Boesenbergia rotunda (L.) Mansf.	Kra-Chai	Root
	Allium ascalonicum L.	Hom-Deng	Bud
	Allium sativum L.	Kra-Theym	Bud
	Ferula assa-foetida L.	Ma-Ha-Hing	Gum resin
	Aloe vera (L.) Burm.f.	Ya-Dam	Gum resin
	Cymbopogon citratus Stapf.	Ta-Khi-Hom	leaves
	Senna siamea (Lam.) Irwin & Barneby	Khi-lek	leaves
	Baliospermum solanifolium (Burm.) Suresh	Tong-Taek	leaves
	Tamarindus indica L.	Ma-Kham	leaves
	Melia azedarach L.	Leyn	leaves
	Drypetes roxburghii (Wall.) Hurusawa	Ma-Kham-Kai	leaves

Table 2 Medicinal plants included in this study (YTPS-DG)

Topicals medication	Scientific name	Thai common name	Use part
Additional herbs (YTPS-DG)	*Sida acuta* Burm.f.	Ya-khad-Mon	Leaf-trunk
	Cleome viscosa L.	Phak-Sein-Phi	Leaf-trunk
	Dimocarpus longan Lour.	Lum-Yai	Seed
	Murraya paniculata (L.) Jack.	Kaew	leaves
	Acmella oleracea (L.) R.K. Jansen	Phak-Khard-How-Wan	plant

The following descriptions elucidate the medicinal properties of the selected herbs:

Sida acuta Burm.f., belonging to the Malvaceae family and commonly referred to as the common wireweed, houses a spectrum of phytochemicals such as alkaloids, flavonoids, and phenolic compounds. These compounds confer the plant with anti-inflammatory, antioxidant, and antimicrobial attributes (Benjumea et al., 2016).

Cleome viscosa L., also known as the Asian spiderflower, is renowned in traditional Ayurvedic medicine. The plant is replete with phytochemicals like glucosinolates, flavonoids, tannins, and terpenes, lending it antioxidant, antimicrobial, and anti-inflammatory properties (Yarrappagaari et al., 2022).

Dimocarpus longan Lour., the tropical tree renowned for its edible longan fruits, is esteemed not merely for its culinary applications but also its medicinal benefits. The seeds, pulp, and flowers are rich in bioactive compounds, such as flavonoids and polyphenols, bestowing antioxidant, anti-inflammatory, and neuroprotective effects. It has found favor in traditional Chinese medicine for calming the spirit, nourishing the blood, and benefiting the spleen and heart (Huang et al., 2012).

Murraya paniculata (L.) Jack, or the orange jasmine/satinwood, is an evergreen shrub distinguished by its fragrant flowers. The plant, particularly its leaves, harbors bioactive compounds like alkaloids, flavonoids, and terpenes, which provide anti-inflammatory, antimicrobial, antioxidant, and anti-tumor properties. It is also recognized for its relaxing and stress-relieving characteristics (Dosoky et al., 2016).

Acmella oleracea (L.) is colloquially known as the toothache plant or tingflowers. Noteworthy for its analgesic properties, particularly in treating toothaches and throat disorders, this plant houses a compound called spilanthol (da Silva et al., 2023). In addition, it exhibits anti-inflammatory, antioxidant, and antimicrobial properties, rendering it a potent ingredient in health-promoting formulas (Tcheghebe et al., 2017; Pillai & Nair, 2014; Zou et al., 2021; Hou et al., 2012; Tansathien, 2022).

The integration of these herbs into the Ya-Tha-Pra-Sen gel formula is anticipated to augment its therapeutic efficacy, potentially improving the overall effectiveness of the medication. This enhancement is particularly pertinent for musculoskeletal disorders that predominantly affect the neck and shoulder regions. Nevertheless, the clinical effectiveness of incorporating these five medicinal herbs remains to be investigated thoroughly.

Despite the known efficacy of the traditional Thai herbal formula Ya-Tha-Pra-Sen in addressing musculoskeletal pain, the influence of augmenting additional medicinal herbs on its potency is less explored. Consequently, this study aims to evaluate the efficacy of a newly developed gel formulation of Ya-Tha-Pra-Sen, fortified with these 5 additional herbs, in alleviating neck and shoulder muscle pain.

2. Objectives

This research is primarily focused on assessing the efficacy of the modified Ya-Tha-Pra-Sen gel formulation with the inclusion of five additional herbs (herein referred to as YTPS-DG). This evaluation is performed in comparison with the traditional Ya-Tha-Pra-Sen formulation (referred to as YTPS-TG).

3. Materials and methods

3.1 Materials

All 18 medicinal plants, as detailed in Table 1 and Table 2, were purchased from Nakhon Pathom (Charoensuk Pharma Supply Co., Thailand) and incorporated into the formulation without undergoing any purification process.

3.2 Methods

3.2.1 Preparation of gel form

Both the traditional Ya-Tha-Pra-Sen formula (YTPS-TG) and the modified Ya-Tha-Pra-Sen formula enriched with five additional herbs (YTPS-DG) were prepared in gel form. For YTPS-TG, all components outlined in Table 1 were combined and thoroughly ground using a mortar and pestle. This was followed by soaking them in 95% ethanol for over a week. The extracts were then filtered using a Gusto-filter cloth. After evaporating, a thick crude extract was obtained and stored in a desiccator.

The YTPS-DG was prepared following the same procedure, with the addition of the five herbs mentioned in Table 2. Both herb extracts were stored at room temperature. The herbal gel was formulated by combining gel agents in the ratio indicated in Table 3, following a method previously described by Toelang et al. (2017). Notably, the herb extracts in each formula were both incorporated at a concentration of 1% w/w.

Table 3 Components of the gel formulas.

chemicals	Master formula (100 g)
1. Carbopol	1 %
2. Triethanolamine	1 %
3. Alcohol	15 %
4. Glycerine	5 %
5. Propylene glycol	20 %
6. Tween80	2 %
7. Menthol: Borneol: Camphor: 2:1:1	4 %
8. Paraben concentrate	0.5 %
9. Crude herbal extract (in alcohol)	1%
10. Distilled water	Absolute

3.2.2 Clinical Trial

The clinical trial received ethical approval from the Rangsit University Ethics Committee (COA. No. RSUERB2020-039). The inclusion criteria encompassed a neck and shoulder muscle pain score of 4 or above, a limited Range of Motion (ROM) in the neck, and the absence of any treatments such as medication, massage, hot compress, or acupuncture within seven days prior to participating in the study.

The sample size was calculated using the G*Power 3.1.94 program, controlling for effect size (f), medium size = 0.25 (Cohen, 1988), error = 0.05, and test power = 0.80, thereby necessitating a total of 45 volunteers. Participants were randomized into one of three treatment groups:

Group 1: YTPS-DG,
Group 2: YTPS-TG,
Group 3: Placebo (PCBG).

The study was conducted at the College of Oriental Medicine at Rangsit University. Participants were given their respective gel in a 2.5 g foil package. They were instructed to apply an equal amount, approximately 2.5 g (the entire content of the package), on both sides of the neck and the upper trapezius muscle area twice a day. They were also asked to assess and rate their pain level using the Visual Analog Scale (VAS) twice a day and to record this information.

The study was conducted over a span of six days with follow-up visits every three days for physical evaluation. During these visits, information regarding muscle pain reduction (VAS), tolerance weight level (kg) of pressure to Trigger Points (TrP) measured by an algometer, and the range of motion (ROM) of the neck and shoulder was collected. Adverse reactions and satisfaction levels of the volunteers were also noted and compared across the three groups.

3.2.3 Statistical analysis

In order to interpret the outcomes of the study, inferential statistical methods were employed. Given the small sample size of this study, non-parametric statistics were selected as the most appropriate analytical tool. For within-group analysis, the Friedman test was utilized to examine the comparative results before and after the continuous three iterations within each of the three groups. The Wilcoxon signed-rank test was employed for within-group comparisons, assessing the volunteers' self-recorded data before and after the study, and analyzing follow-up data comparing baseline versus the first visit, and the first visit versus the second visit. For intergroup comparisons, the Mann-Whitney U test was used to determine significant differences between the two groups.

4. Results

A total of 45 volunteers participated in this clinical research. The characteristics of all participants were compiled and are presented in Table 4. The participants were divided into three groups: a group using the newly formulated YTPS-DG gel, a group using the traditional YTPS-TG gel, and a group using a placebo gel, with 15 participants in each group. A majority of the

volunteers were female (75.6%) and were between the ages of 20-35 years. All of the participants were non-smokers, did not consume alcohol, and had no pre-existing diseases before commencing the trial. The muscle pain levels were recorded and are shown that there were no significant differences in the initial characteristics among the groups. It is noteworthy that no adverse effects were observed in any group by the end of the study.

4.1 Reduction in Muscle Pain

Upon six days of gel application, the non-parametric analysis (as shown in Table 5) revealed a significant difference in muscle pain reduction between the YTPS-DG group and both the YTPS-TG group (U = 66.00, p = 0.048) and the placebo group (U = 63.00, p = 0.036). However, no significant difference in pain reduction was observed between the YTPS-TG group and the placebo group ($P > 0.05$). These findings suggest that the newly developed YTPS-DG formulation was the most effective in reducing pain, both within its own group and when compared to the traditional YTPS-TG and the placebo group, with statistical significance ($P < 0.05$).

Figure 1 further illustrates the comparative effectiveness of the three treatments over the course of the study (from the initial visit, the first follow-up on day 3, to the second follow-up on day 6). The YTPS-DG group (red bar) demonstrates a consistent trend of pain reduction, whereas the YTPS-TG (yellow bar) and placebo groups (green bar) show a decrease in pain levels only for the first three days, followed by a steady state for the remaining days. This supports the conclusion that YTPS-DG had a superior effect on muscle pain reduction.

Table 4 Characteristics of the 3 groups of volunteers before the study.

Title	Study groups				*P*-value
	Total (N=45)	YTPS-DG (n=15)	YTPS-TG (n=15)	PCBG (n=15)	
1. Gender: person (%)					
- female:	34 (75.6)	13 (86.7)	11 (73.3)	10 (66.7)	**0.689****
- male:	11 (24.4)	2 (13.3)	4 (26.7)	5 (33.3)	
2. Age Group: People (%)					
- 20 - 35 years	42 (93.3)	14 (93.3)	14 (93.3)	14 (93.3)	**1.000***
- 36 – 60 years	3 (6.7)	1 (5.7)	1 (5.7)	1 (5.7)	
3. Occupation: Person (%)					
- Student	42 (93.3)	14 (93.3)	14 (93.3)	14 (93.3)	**0.558***
- Lecturer at Rangsit University	1 (5.9)	1 (6.7)	-	-	
- Housewives/Staff within Rangsit University	2 (4.4)	-	1 (6.7)	1 (6.7)	
4. Have disease: person (%)	NA	NA	NA	NA	NA
5. Drink alcohol: person (%)	NA	NA	NA	NA	NA
6. Smoking: person (%)	NA	NA	NA	NA	NA
7. Having treatment for neck, and shoulder, muscle for at least 7 days before participating this research	NA	NA	NA	NA	NA
8. Pain group: person (%)					
- no pain (level 0)	-	-	-	-	-
- Mild pain (level 1-3)	-	-	-	-	-
- Moderate pain (level 4-5)	32 (71.1)	8 (53.3)	12 (80.0)	12 (80.0	
- Severe pain (level 6-7)	12 (26.7)	7 (46.7)	2 (13.3)	3 (20.0)	
- Most pain (level 8-9)	1 (2.2)	-	1 (6.7)	-	
- severe Pain (level 10)	-	-	-	-	
- median (IQR)	4 (4,6)	5 (4,6)	4 (4,5)	4 (4,4)	

**Statistical analysis: Pearson Chi-Square, ** Statistical analysis: Fisher's Exact Test, P-value < 0.05*

Table 5 Comparison of the neck, shoulder, and shoulder muscle pain scores (VAS), the results comparing within group and between groups.

Study topic	The results Classified according to the formula studied					
	YTPS-TG (n=15)		YTPS-DG (n=15)		PCBG (n=15)	
	Baseline	Visit 2	Baseline	Visit 2	Baseline	Visit 2
pain levels Median	4 (4,5)	2 (2,4)	5 (4,6)	2 (1,3)	4 (4,4)	3 (2,4)
***P*-value**		**0.006***		**< 0.001***	-	**0.011***
Between groups (*U, P*-value)**						
YTPS-TG vs YTPS-DG	[……..…..……**66.00, 0.048****……..……]					
YTPS-DG vs PCBG			[……..……**63.00, 0.036****……..……..]			
YTPS-TG vs PCBG	[……..……..……] ◆				[…111.50, 0.967.....]	

*(median Quartiles) *Statistic analysis: Friedman **Statistic analysis: Mann-Whitney Test, statistical significance = p<0.05*

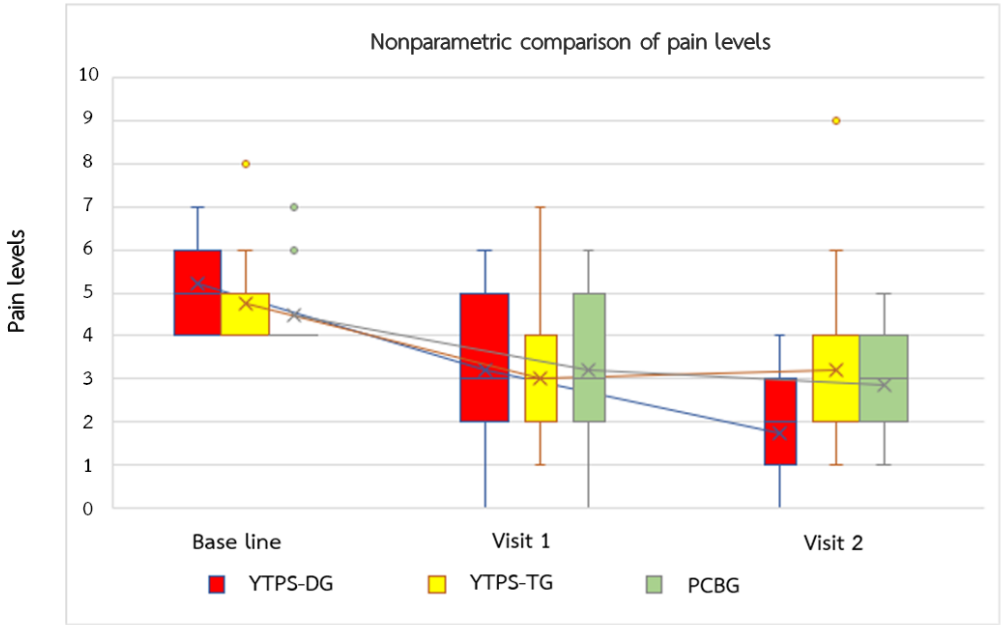

Figure 1 Comparison of the median pain levels between groups, including, YTPS-DG, YTPS-TG, and PCBG

Table 6 outlines the within-group comparison for muscle pain reduction from the start of the study to day 6 following the application of YTPS-DG. The results clearly indicate that the average pain score significantly decreased from level 5 to level 2 over the course of six days. The statistical analysis revealed a significant reduction in pain levels within the group before and after the study period ($P < 0.001$).

4.2 Range of Motion (ROM)

The variations in the Range of Motion (ROM) of the neck, measured in degrees, are presented in Table 6. The data indicate a significant increase (P <0.05) in the neck motion angle, specifically in cervical extension ($P = 0.012$), right side-bending ($P = 0.025$), and left side-bending ($P = 0.026$). However, cervical flexion did not show a significant difference ($P = 0.052$), suggesting that no observable improvement was noted for this parameter. These results imply that the application of YTPS-DG may have contributed to an increased range of motion in the neck for the volunteers within the group. However, no significant differences were observed between the groups in this regard.

4.3 Tolerance Weight Level (kg)

Table 6 also presents the results related to the differences in the tolerance weight level. Within the YTPS-DG group, there was a statistically significant increase (P <0.05) in the median score for tolerance of pressure levels on both the right TrP (P = 0.034) and the left TrP (P = 0.034). However, no significant difference was reported when comparing the YTPS-DG group with either the YTPS-TG or the PCBG group. This outcome may potentially be attributed to the relatively small sample size, which could have limited the power to detect any difference.

5. Discussion

The statistical analysis, conducted via Wilcoxon sign rank test and Friedman statistical test, indicates that YTPS-DG demonstrates an increased effect within the groups regarding tolerance weight level exerted on the Trigger Point (TrP) and the range of motion (ROM) degree of the neck from the baseline. These outcomes may be attributed to the medicinal properties of the five additional herbs, particularly the anti-inflammatory characteristics of *Sida acuta Burm.* f., *Murraya paniculata* (L.) Jack., and *Cleome viscosa* L. extract (Pillai & Nair, 2014; Zou et al., 2021). Additionally, the influence of *Dimocarpus longan* Lour. Seed extract's xanthine oxidase activity on gout and osteoarthritis treatment could also be contributive (Hou et al., 2012). The results suggest that YTPS-DG performs more effectively on VAS, ROM, and TrP than YTPS-TG, exhibiting a trend towards consistent pain reduction and potentially shortening treatment time. Nevertheless, this research found no significant difference between groups in terms of tolerance weight level exerted on the Trigger Point (TrP), which may be due to the duration and frequency of usage or an insufficient sample size. No adverse effects were reported for all the three groups, but prior studies have noted potential side effects of YTPS such as redness, itching, and irritation (Kanokkangsadal et al., 2020; Roiet et al., 2019; Meekai et al., 2021).

Table 6 Comparison within group of pain score (VAS) of neck and shoulder muscles, range of motion (ROM) of neck, and tolerate weight level (Kg); before and after applying the YTPS-DG.

Title	YTPS-DG (n=15) Median (Quartiles)			before-after
	Baseline	**Visit 1**	**Visit 2**	***P*-value****
pain scores (VAS)	5 (4,6)	3 (2,5)	2 (1,3)	**< 0.001****
*Z, P-value**	-	**3.01, 0.003***	**2.65, 0.008***	
Range of motion (ROM) of neck (degree)				
Cervical flexion (Mdn)	32 (24,40)	36 (30,45)	41 (37,47)	0.052
Z, P-value	-	0.63, 0.530	1.26, 0.209	
Cervical extension	44 (30,55)	46 (36,55)	54 (47,60)	**0.012****
Z, P-value	-	1.28, 0.201	**2.22, 0.027***	
Right side-bending	31 (27,37)	41 (33,46)	39 (37,44)	**0.025****
Z, P-value	-	**1.96, 0.050***	0.43, 0.670	
Left side-bending	35 (29,43)	40 (33,45)	44 (37,49)	**0.026****
Z, P-value	-	1.76, 0.078	1.14, 0.255	
Tolerate weight level (kg.)				
Right TrP	33.90 (31.00,55.80)	50.15 (35.40,52.25)	50.35 (44.55,65.70)	**0.034****
Z, P-value	-	1.02, 0.307	1.70, 0.88	
Left TrP	40.80 (29.85,57.20)	44.80 (33.05,56.78)	49.95 (44.95,65.85)	**0.005****
Z, P-value	-	1.83, 0.067	**2.90, 0.004***	

Statistical analysis: **Significance under Wilcoxon sign rank test (p<0.05)*
*** Significance under Friedman statistical significance (p<0.05)*

6. Conclusion

Ya-Tha-Pra-Sen, a traditional medicine, has been utilized for centuries to treat muscle pain. This study substantiates the positive effect of adding five Thai herbs - *Sida acuta Burm.*f., *Cleome viscosa* L., *Dimocarpus longan* Lour., *Murraya paniculata* (L.) Jack., and *Acmella oleracea* (L.) - to the formulation. The modified formula of Ya-Tha-Pra-Sen mixed with these five herbs was evaluated in a randomized controlled clinical trial against the traditional Ya-Tha-Pra-Sen formula, with a placebo group included to mitigate the placebo effect.

By assessing the clinical effectiveness of this modified formula (YTPS-DG), this study points to its potential in enhancing pain scores (VAS), Range of Motion (ROM), and tolerance weight level of pressing to the Trigger Point (TrP). These findings suggest the potential benefits of adding other herbs to Ya-Tha-Pra-Sen to enhance its effectiveness, potentially providing greater relief for patients suffering from musculoskeletal issues.

The modified Ya-Tha-Pra-Sen formula should be further explored for development as a topical product in gel or cream form, given its numerous positive effects on pain reduction. Furthermore, further research should be conducted to determine the optimal percentage of herbal extracts to use. It is also recommended to consider developing a Ya-Tha-Pra-Sen modified formula in an oil or cream form suitable for use with massage.

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