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The Effects of Self-Aromatherapy Massage on Pain and Sleep Quality in Patients with Rheumatoid Arthritis: A Randomized Controlled Trial



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ABSTRACT

Background: Rheumatoid arthritis is the most common form of inflammatory arthritis and can lead to pain, joint deformity, and disability, resulting in poor sleep quality and lower quality of life. The efficacy of aromatherapy massage on pain levels and sleep quality among rheumatoid arthritis patients remains unclear.

Aims: To investigate the effects of aromatherapy on pain and sleep quality among rheumatoid arthritis patients.

Methods: This randomized controlled trial enrolled 102 patients with rheumatoid arthritis from one regional hospital in Taoyuan, Taiwan. Patients were randomly assigned to the intervention (n = 32), placebo (n = 36), or control groups (n = 34). The intervention and placebo groups underwent self-aromatherapy hand massage guided by a self-aromatherapy hand massage manual and video for 10 minutes 3 times a week for 3 weeks. The intervention group used 5% compound essential oils, the placebo group used sweet almond oil, and the control group had no intervention. Pain, sleep quality and sleepiness were measured by using the numerical rating scale for pain, the Pittsburgh Sleep Quality Index and the Epworth Sleepiness Scale at baseline and at 1, 2, and 3 weeks after the intervention.

Results: The intervention and placebo groups had significantly decreased sleep quality and sleepiness scores from baseline to 3 weeks after aromatherapy massage. Compared with the control group, the intervention group showed statistically significant improvement in the sleep quality scores in the first weeks after aromatherapy massage (B = -1.19, 95% confidence interval [CI]: -2.35, -0.02, P = .046), but no statistically significant differences were found in the changes in pain levels from baseline to the three time points.

Conclusions: Aromatherapy massage is effective in improving sleep quality in rheumatoid arthritis patients. More studies are needed to evaluate the effects of aromatherapy hand massage on the pain levels of rheumatoid arthritis patients.

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Rheumatoid arthritis (RA) is a common inflammatory arthritis that primarily involves synovial joints and affects approximately 0.5-1.0% of the population (Littlejohn & Monrad, 2018; Mohammed et al., 2020). Without appropriate treatment, RA can lead to joint deformity and disability. Patients with RA may suffer from symptoms including pain, morning stiffness, and swelling of many joints, especially the small joints of the hands and feet, and the symptoms are usually symmetrical. Most patients with RA have slight pain (61.6%) or moderate pain (24.7%) (Vergne-Salle et al., 2020). The most frequently reported areas with chronic pain were the hands/lower arms (88%) or feet/lower leg (83%) (Ryan & McGuire, 2016). Previous studies have shown that pain may affect patients' daily lives, including work and physical function, and is correlated with anxiety, depression, and poor sleep quality (Albayrak Gezer et al., 2017; Rosa-Gonçalves et al., 2018). Therefore, it is important to manage pain and improve the sleep quality of patients with RA.

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Poor sleep quality has been reported in 57.6% to 81.5% of patients with RA (Albayrak Gezer et al., 2017; Goes et al., 2017; Guo et al., 2016). Pain, comorbidities, disease activity, and medications may contribute to poor sleep quality, which may result in exacerbated inflammation, mental and physical fatigue, mood disorders, daytime sleepiness, and lower quality of life (Coskun Benlidayi, 2018; Guo et al., 2016; Szady et al., 2017). Although pain and sleep disturbance could be improved by medications such as disease-modifying anti-rheumatic drugs, nonsteroidal antiinflammatory drugs, biologics, and sleep medicine (Detert et al., 2016), patients may suffer from adverse effects of these medications, such as infection, gastrointestinal bleeding, constipation, nausea, and vomiting. In addition to the use of medications, patients may use complementary and alternative medicine (CAM) to manage chronic pain due to dissatisfaction with the side effects and drug ineffectiveness of conventional treatment (Phang et al., 2018).

The prevalence of CAM use was reported to be 59.2% among patients with RA, and the most commonly used CAM was herbal remedies and supplements, menthol-based and arnica ointments (35%), or aromatherapy massage (Caballero-Hernandez et al., 2021). Most patients with RA (62.3%) reported little or no improvement in their symptoms from CAM (Caballero-Hernandez et al., 2021). However, a systematic review indicated that massage therapy was superior to nonactive therapies in reducing pain for patients with arthritis (Nelson & Churilla, 2017). In addition, a systematic review and meta-analysis showed that aromatherapy could reduce pain levels (Lakhan et al., 2016). Previous studies reported that aromatherapy massage could improve pain levels in patients with knee osteoarthritis (OA) (Efe Arslan et al., 2019; Gok Metin & Ozdemir, 2016; Nasiri et al., 2016; Tuna et al., 2018). However, the efficacy of aromatherapy hand massage on pain levels and sleep quality among patients with RA remains unclear. Therefore, this study aims to evaluate the effects of self-aromatherapy hand massage on pain levels and sleep quality among patients with RA.

Methods

Study Design

This study was a parallel randomized controlled trial (trial registration: ClinicalTrials.gov: NCT04549857, September10, 2020). The participants were randomly assigned to the intervention group (n = 32), the placebo group (n = 36), or the control group (n = 34). Data were collected by a research assistant at baseline and 1 week, 2 weeks, and 3 weeks after enrolment. This study complied with the CONsolidated Standards Of Reporting Trials (CONSORT) checklist.

Participants and Setting

Patients with rheumatoid arthritis were recruited using convenience sampling from the rheumatology and immune outpatient department of one regional hospital in Taoyuan, Taiwan. The inclusion criteria for the participants were: (1) aged 20 years or older; (2) diagnosed with RA; (3) willing to communicate and participate in this study; and (4) had equipment to watch videos. Patients were excluded if they had: (1) an allergy to essential oils; (2) a wound or surgery on the hand or wrist; (3) contraindications to aromatherapy, e.g., epilepsy or pregnancy; or (4) received physical therapy or hormone replacement therapy.

During the study period from November 2020 to May 2021, 146 patients were eligible for inclusion. Among them, 44 patients refused to participate in this study because of insufficient time (n = 20), the study felt troublesome (n = 16), and lack of interest (n = 20)

= 8). In total, 102 patients were enrolled and randomly assigned to the intervention group (n = 32), the placebo group (n = 36), or the control group (n = 34). Seven patients were lost to follow-up during the 3-week follow-up. Finally, 95 patients completed the entire study, with an attrition rate of 6.8% (Fig. 1). The researcher used a computerized random number generator to generate a sequence for the intervention, placebo and control groups using a block randomization method in blocks of 6 at a 1:1:1 ratio. The allocation was kept in sequentially numbered, opaque envelopes. Using the G-power procedure, an estimated sample size of 102 was required to reach sufficient power of 0.8 with an alpha of 0.05 and an effect size of 0.25 following a previous study (Nasiri et al., 2016).

Ethical Consideration and Data Collection

This study was conducted under the principles of the Declaration of Helsinki. The study was approved by the Institutional Review Board of Taoyuan General Hospital, Ministry of Health and Welfare (TYGH108056). The researcher explained the study purpose, methods, and procedures and obtained informed consent from the participants who met the inclusion criteria and were willing to participate in the study. The participants' right to withdraw at any time was assured, and their data were kept confidential. Data were collected by a research assistant using a structured questionnaire at baseline and 1 week, 2 weeks, and 3 weeks after enrolment. The research assistant was blinded to the group allocation. A pilot study (n = 6) was conducted to test the usefulness of the measurements and the applicability of self-aromatherapy with massage. The participants' data in the pilot study were included in the final data analysis.

Measures

Primary outcome

Pain levels were measured by using the numerical rating scale for pain (NRS pain) (Hawker et al., 2011). It is a unidimensional measure of pain intensity with an 11-point numeric scale (0 = nopain, 10 = worst pain). Higher scores indicate greater pain intensity. High test-retest reliability (r = .95-.96) and a construct validity that is highly correlated with the Visual Analogue Scale (r = .86-.95) have been reported in patients with RA (Hawker et al., 2011).

Secondary outcome

Sleep quality was measured by using the Pittsburgh Sleep Quality Index (PSQI) and Epworth Sleepiness Scale (ESS). The PSQI is a self-rated scale that includes seven component scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction (Buysse et al., 1989). The total score ranged from 0-21, with higher scores indicating poor sleep quality. A score greater than 5 indicated poor sleep and yielded a diagnostic sensitivity of 89.6% and specificity of 86.5%. The reliability was acceptable, with Cronbach's alpha coefficients of 0.83 in healthy and sleep-disorder subjects (Buysse et al., 1989) and 0.73 in patients with RA (Nicassio et al., 2014). In this study, the Cronbach's alpha of the PSOI was 0.67.

The Epworth Sleepiness Scale (ESS) measures the subject's general level of daytime sleepiness in eight common daily activities, e.g., sitting and reading, sitting inactive in a public place, sitting and talking to someone, or sitting quietly after lunch without alcohol (Johns, 1991). The ESS is rated on a 4-point scale (0-3), and the total score ranges from 0-24, with higher scores indicating higher daytime sleepiness. An ESS score >10 suggests excessive daytime sleepiness. The ESS showed acceptable internal consistency (Cronbach's alpha = 0.81) and test-retest reliability (r = .74) among Chi-

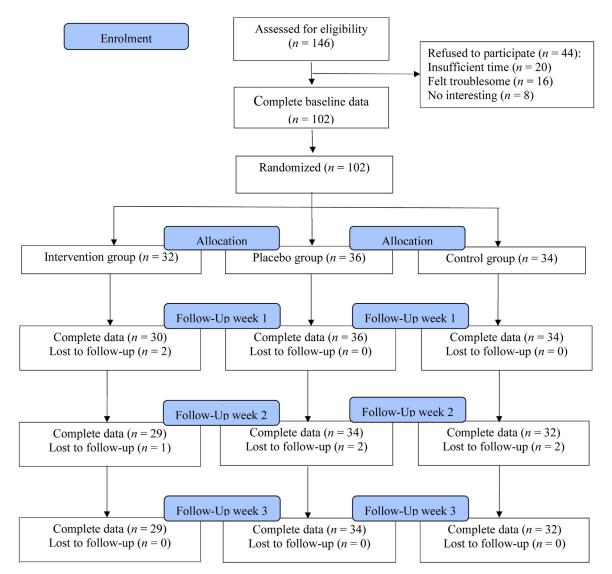


Figure 1. CONSORT flowchart of the study. CONSORT = Consolidated Standards of Reporting Trials.

nese patients with sleep-disordered breathing. The Cronbach's alpha coefficient is 0.67 in this study.

Covariates

The demographic characteristics consisted of age, sex, education, marital status, and work status. The clinical characteristics included disease duration, comorbidity, medications, CRP, erythrocyte sedimentation rate (ESR), stiffness, joint deformity, fatigue, and the Disease Activity Score in 28 joints (DAS28). Fatigue was measured by asking the patient's perceived level of fatigue from 0 (no fatigue) to 10 points (very high fatigue). The DAS28 was computed utilizing the number of swollen and painful joints (out of 28 joints), ESR, and overall assessment of disease activity on a visual analogue scale of 0-10 (Kumar et al., 2017). The patients were classified as having very active disease (DAS28 >5.1), active disease (5.1-3.2), low disease activity (2.6-3.2), and remission (<2.6).

Interventions

The intervention group and the placebo group performed selfaromatherapy hand massage for 10 minutes 3 times a week for 3 weeks. The frequency and duration for massage intervention were decided based on a literature review of previous studies focusing on the effects of aromatherapy massage on patients with arthritis. Most studies performed aromatherapy massage 3 times per week (Efe Arslan et al., 2019; Gok Metin & Ozdemir, 2016; Tuna et al., 2018) and for 3 weeks (Efe Arslan et al., 2019; Nasiri & Mahmodi, 2018; Nasiri et al., 2016). The intervention group used 5% compound essential oils (Cedarwood Atlas, Sweet Marjoram, Sweet Orange 3:1:1 in Sweet Almond oil), the placebo group used Sweet Almond oil, and the control group did not receive any intervention. We used 5% compound essential oils (Cedarwood Atlas, Sweet Marjoram, Sweet Orange 3:1:1 in sweet almond oil) because these oils have antiarthritic, pain relief, and anti-inflammation effects. Sweet Marjoram essential oil may suppress the production of tumor necrosis factor-a, interleukin 1b (IL-1b), IL-6, and IL-10 and inhibit cyclooxygenase 2 and NFkB gene expression (Bina & Rahimi, 2017). In addition, Cedarwood Atlas essential oil had analgesic and anti-inflammatory sedative effects. It may relieve pain by activating the descending pain modulation pathways on the opioidergic, serotonergic, noradrenergic (α 2-adrenergic), and dopaminergic systems (Martins et al., 2015).

First, the researcher performed a 30-minute individual education of the self-aromatherapy hand massage technique with the aromatherapy manual and video for the intervention and placebo groups in a calm environment; these materials were developed by the researcher and modified from the AromaTouch Hand Technique by doTERRA® (AromaTouch, 2018). The selfaromatherapy manual included an introduction of aromatherapy, the self-aromatherapy hand massage technique with step-by-step pictures, and the performance record form. The self-aromatherapy hand massage technique included four steps: (1) oil introduction: an even coating of 2.5 ml oils is applied to the entire palm of the left hand (take 30 seconds); (2) regional tissue pressing: while palm of the left hand is facing upwards, the thumbs of the right hand are used to work the oils into to the entire palm of left hand with a moderate amount of pressure (30 seconds); (3) interphalangeal tissue pressing: the thumbs of the right hand are used to work the oils into the skin of each finger of the left hand and from the wrist to the tip of finger. The procedure was repeated for all five zones, with three times each zone (3 minutes); (4) pressing the tissue of the palm: the right hand is used to press the tissue of the palm located between each finger. The procedure is then repeated three times for each finger (1 minute). The process is then repeated on the right hand. Each hand takes 5 minutes. The entire self-aromatherapy hand massage takes 10 minutes. The teach-back method was used in this study to assure the accuracy of the patients' performance of the self-aromatherapy hand massage technique.

Second, the intervention and placebo groups performed selfaromatherapy hand massage at home for 10 minutes each, 3 times per week for 3 weeks, guided by the self-aromatherapy manual and video, and completed the performance record. Then, the researcher monitored the participants' performance of the self-aromatherapy hand massage through weekly telephone interviews in the intervention and placebo groups. No adverse effects of self-aromatherapy with massage were reported by the intervention and placebo groups in this study. For those participants who are unable to perform hand massage due to hand deformities, their families may perform hand massage for them. Only one participant in the placebo group was affected by hand deformities, and the hand massage was performed by her daughter.

Intervention fidelity was ensured through the following process. The intervention was delivered by the same researcher based on the standard protocol. During the implementation of the selfaromatherapy hand massage, the researcher performed a 30minute individual education of the self-aromatherapy hand massage technique with the aromatherapy manual and video. The accuracy of the patients' performance of the self-aromatherapy hand massage technique was assured by using the teach-back method. Within 1 week after education, the researcher conducted a telephone follow-up interview with each participant to ensure his or her understanding of the intervention and evaluate the patient's achievement of the intervention. Then, the researcher monitored the participants' performance and adherence to the frequency of the intervention by using the participant's performance record and telephone interviews weekly with social media such as LINE (software), which offered free smartphone calls and texting.

Statistical Analysis

The data were analyzed using IBM SPSS (version 24, Chicago, Illinois, USA). This study used intention-to-treat analysis, which means that all patients (n = 102) were analyzed in the group to which they were originally assigned. The homogeneity of the demographic and clinical information and the pain and sleep quality scores among the three groups at baseline were tested by $\chi 2$ tests and one-way analysis of variance. Generalized estimating equa

tions (GEEs) were used to compare within-group differences in the pain, PSQI, and ESS scores over the 3 weeks among the intervention, placebo and control groups, as well as to examine between-group differences in the changes over time (i.e., baseline, 1 week, 2 weeks, 3 weeks). The GEE model was used with the identity link function and the autoregressive (AR[1]) correlation structure because pain and sleep quality are continuous outcomes and tend to be more correlated when assessments are closer in time. A *p* value < .05 was considered statistically significant.

Results

Patient Characteristics, Pain Levels, and Sleep Quality at Baseline in the Three Groups

The mean age of all patients was 54.25 years (SD = 12.04). The majority of the patients were women (80.4%), married (67.7%) and had >9 years of education (68.6%). Most of the patients reported pain (72.6%), fatigue (72.6%), and stiffness (56.9%); deformities were reported in 49% of patients. The mean disease duration was 8.20 (SD = 7.66), and the mean DAS28 was 3.89 (1.31), indicating active disease. The most commonly used drugs were disease-modifying anti-rheumatic drugs (97.1%), nonsteroidal antiinflammatory drugs (68.6%), and biologics (63.7%). The mean pain and fatigue scores were 3.16 (SD = 2.82) and 4.01 (SD = 3.16), respectively. A total of 72.55% of the patients with RA reported pain. The PSOI and ESS scores were 7.56 (SD = 3.70) and 5.93 (SD = 3.70), respectively. Poor sleep quality (PSQI >5) was found in 63.72% of the patients, and 8.82% of the patients had excess daytime sleepiness (ESS > 10). This finding indicated that most patients with RA have poor sleep quality. There were no statistically significant differences among the control group, placebo, and intervention group at baseline in the demographic and clinical characteristics, except for stiffness, deformity, pain, fatigue, and sleep medicine (Table 1).

Effects of Self-aromatherapy Hand Massage on the Pain Levels at Different Time Points Among the Three Groups

Table 2 shows that the pain levels of the intervention group were slightly increased from 3.67 (SD = 3.12) at baseline to 3.85 (SD = 2.17) at the first week and 3.71 (SD = 2.08) at the second week after intervention and then decreased to 3.31 (SD = 2.43) at the third week. GEE analysis showed no statistically significant differences in the pain levels of the intervention group at different time points compared to baseline (p = .501). The pain levels of the placebo group were slightly increased from 3.57 (SD = 2.68) at baseline to 3.67 (SD = 2.31) at the first week and then decreased to 3.07 (SD = 2.67) and 2.90 (SD = 2.33); a statistically significant difference was found between the first week and third week (p = .029). The pain levels of the control group showed no statistically significant changes from baseline to the third week after enrolment (p = .705).

A GEE model was used to test for differences between the intervention, placebo, and control groups with respect to changes in the pain levels from baseline (T_0) to 1 week (T_1), 2 weeks (T_2) and 3 weeks (T_3), after being adjusted for covariates including stiffness, deformity, pain, fatigue, and sleep medicine. Compared with the control group, both the patients in the intervention and the placebo groups exhibited no statistically significant changes in pain levels at all time points (Fig. 2). This result indicated that selfaromatherapy hand massage had no statistically significant effects on the pain levels of patients with RA.

Table 1

Homogeneity of the Participants' Characteristics at Baseline Between the Three Groups (n = 102).

	All (n = 102) n (%)	Control (n = 34) n (%)	Placebo (n = 36) n (%)	Intervention $(n = 32)$ n (%)	x ²	р
Sex					0.65	.721
Female	82 (80.4)	26 (76.5)	29 (80.6)	27 (84.4)		
Male	20 (19.6)	8 (23.5)	7 (19.4)	5 (15.6)		
Work status					5.71	.058
Unemployed	45 (44.1)	15 (44.1)	11 (30.6)	19 (59.4)		
	57 (55.9)	19 (55.9)	25 (69.4)	13 (40.6)		
Education					1.36	.507
≤9 y	32 (31.4)	13 (38.2)	11 (30.6)	8 (25.0)		
	70 (68.6)	21 (61.8)	25 (69.4)	24 (75.0)		
Marital status					0.41	.814
Single	33 (32.3)	12 (35.3)	12 (33.3)	9 (28.1)		
Married	69 (67.7)	22 (64.7)	24 (66.7)	23 (71.9)		
Stiffness (yes)	58 (56.9)	13 (38.2)	20 (55.6)	25 (78.1)	10.73	.005
Deformity (yes)	50 (49.0)	14 (41.2)	13 (36.1)	23 (71.9)	9.93	.007
Pain (yes)	74 (72.6)	19 (55.9)	30 (83.3)	25 (78.1)	7.34	.025
Fatigue (yes)	74 (72.6)	19 (55.9)	28 (77.8)	27 (84.4)	7.48	.024
Sleep medicine	12 (11.8)	0	5 (13.9)	7 (21.9)	7.84 ^a	.020
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	F	р
Age (y)	54.25 (12.04)	54.94 (12.63)	52.61 (11.53)	55.38 (12.15)	0.52	.594
Disease duration	8.20 (7.66)	9.35 (8.39)	6.16 (6.05)	9.27 (8.21)	2.02	.139
CRP	0.48 (1.24)	0.55 (0.98)	0.20 (0.39)	0.72 (1.92)	1.55	.218
ESR	31.29 (24.35)	31.88 (24.72)	28.50 (21.57)	33.81 (27.20)	0.41	.663
DAS28	3.89 (1.31)	3.46 (0.98)	3.99 (1.24)	4.22 (1.57)	3.06	.051
Comorbidity	0.60 (0.87)	0.53 (0.86)	0.56 (0.74)	0.72 (1.02)	0.45	.638
Fatigue score	4.01 (3.16)	3.29 (3.37)	4.50 (2.98)	4.22 (3.08)	1.39	.254
Pain score	3.16 (2.82)	2.24 (2.50)	3.57 (2.68)	3.67 (3.12)	2.83	.064
PSQI	7.56 (3.70)	6.74 (3.51)	7.22 (3.67)	8.81 (3.70)	2.94	.057
ESS	5.93 (3.70)	5.47 (4.13)	6.44 (2.70)	5.84 (4.21)	0.61	.544

SD = standard deviation; CRP = C-reactive protein; ESR = erythrocyte sedimentation rate; DAS28 = Disease Activity Score in 28 joints; PSQI = Pittsburgh Sleep Quality Index; ESS = Epworth Sleepiness Scale.

Table 2

Group Differences in the Effects of Aromatherapy on the Pain Scores Over Time (N = 102).

1	15		,			
Group	Baseline (T ₀) Mean (SD)	Week 1 (T ₁) Mean (SD)	Week 2 (T ₂) Mean (SD)	Week 3 (T ₃) Mean (SD)	р	
Control	2.24 (2.50)	2.59 (2.63)	2.08 (2.05)	2.22 (2.66)	.705	
Placebo	3.57 (2.68)	3.67 (2.31)	3.07 (2.67)	2.90 (2.33)	$.029^{a}(T_{1} > T_{3})$	
Intervention	3.67 (3.12)	3.85 (2.17)	3.71 (2.08)	3.31 (2.43)	.501	
			95% Wald <i>Cl</i>			
	В	SE	Lower	Upper	р	
Intercept	0.49	0.49	-0.47	1.44	.317	
group						
Intervention	0.37	0.59	-0.80	1.53	.536	
Placebo	0.58	0.56	-0.52	1.68	.303	
Time						
Week 3 (T_3)	-0.43	0.79	-1.98	1.13	.852	
Week 2 (T ₂)	0.05	0.76	-1.44	1.54	.971	
Week 1 (T ₁)	-0.10	0.65	-1.37	1.17	.429	
Group * Time						
Intervention * T ₃	-0.43	0.79	-1.98	1.13	.591	
Intervention * T ₂	0.05	0.76	-1.44	1.54	.951	
Intervention * T ₁	-0.10	0.65	-1.37	1.17	.879	
Placebo * T ₃	-0.85	0.77	-2.36	0.65	.266	
Placebo * T ₂	-0.59	0.73	-2.03	0.85	.421	
Placebo * T ₁	-0.26	0.62	-1.47	0.96	.681	

^a p < .05.

Outcome variables: Pain score. Covariates: stiffness, deformity, pain, fatigue, sleep medicine. A generalized estimating equation (GEE) model was used to test for differences between the intervention, placebo and control groups with respect to changes from baseline (T_0) to 1 week (T_1) , 2 weeks (T_2) and 3 weeks (T_3) after adjusting for covariates. Reference group: control group * at baseline.

SD = standard deviation; SE = standard error; CI = confidence interval.

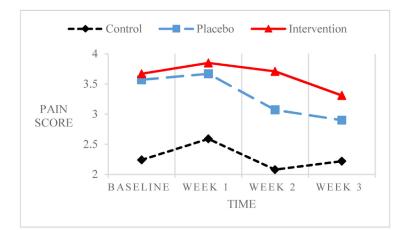
Effects of Self-aromatherapy Hand Massage on Sleep Quality at Different Time Points Among the Three Groups

7.03 (SD = 3.61) at the first week and 7.38 (SD = 3.87) at the second week and then decreased to 6.79 (SD = 4.35) at the third week based on GEE analysis (p =.005).

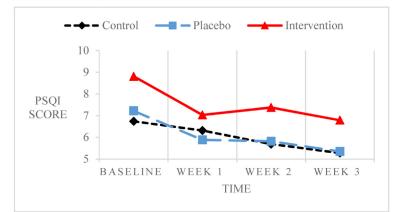
Table 3 shows that the PSQI scores of the intervention group were significantly decreased from 8.81 (SD = 3.70) at baseline to

The PSQI scores of the placebo group also significantly decreased from 7.22 (SD = 3.67) at baseline to 5.89 (SD = 3.25) at

a. Pain score



b. Pittsburgh Sleep Quality Index (PSQI)



c. Epworth Sleepiness Scale (ESS)

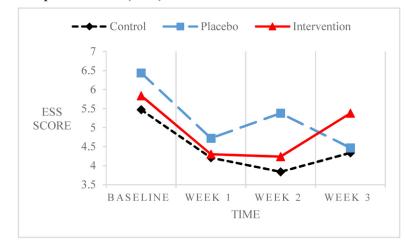


Figure 2. Comparison of the pain and sleep quality scores among the groups over the 3-week follow-up period. A. Pain score. B. Pittsburgh Sleep Quality Index (PSQI). C. Epworth Sleepiness Scale (ESS).

the first week, to 5.82 (SD = 3.42) at the second week and to 5.35 (SD = 3.34) at the third week (p = .001). The PSQI scores of the control group showed no statistically significant changes from baseline to the third week after enrolment (p =.145). Compared with the control group, the patients in the intervention group exhibited a statistically significant change in the PSQI scores from

baseline to the first week (B = -1.19, 95% CI: -2.35, -0.02, p = .046). This indicated that self-aromatherapy hand massage had statistically significant effects on the sleep quality of patients with RA in the first week after intervention. Compared with the control group, the patients in the placebo groups exhibited no statistically significant changes in the PSQI scores at all time points (Fig. 2).

Table 3

Group Differences in the Effects of Aromatherapy on Sleep Quality Over Time (N = 102).

		PSQI score			
Group	Baseline (T ₀) Mean (SD)	Week 1 (T ₁) Mean (SD)	Week 2 (T ₂) Mean (SD)	Week 3 (T ₃) Mean (SD)	р
Control	6.74 (3.51)	6.32 (3.67)	5.69 (3.26)	5.28 (2.66)	.145
Placebo	7.22 (3.67)	5.89 (3.25)	5.82 (3.42)	5.35 (3.34)	.001
Intervention	8.81 (3.70)	7.03 (3.61)	7.38 (3.87)	6.79 (4.35)	.005
			95% V	/ald CI	
	В	SE	Lower	Upper	р
Intercept group	5.89	0.75	4.42	7.36	<.00
Intervention	0.60	0.85	-1.08	2.27	.485
Placebo	-0.51	0.80	-2.08	1.05	.520
Time					
Week 3 (T ₃)	-1.29	0.62	-2.51	-0.07	.038ª
Week 2 (T ₂)	-0.83	0.54	-1.89	0.24	.127
Week 1 (T_1)	-0.41	0.41	-1.21	0.39	.313
Group * Time					
Intervention * T ₃	-0.61	0.90	-2.37	1.16	.500
Intervention * T ₂	-0.46	0.79	-2.00	1.09	.562
Intervention $* T_1$	-1.19	0.59	-2.35	-0.02	.046
Placebo * T ₃	-0.66	0.87	-2.36	1.04	.446
Placebo * T_2	-0.66	0.76	-2.15	0.82	.382
Placebo * T_1	-0.92	0.57	-2.04	0.19	.105
		ESS score			
Group	Baseline (T ₀)	Week 1 (T_1)	Week 2 (T_2)	Week 3 (T_3)	р
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	1
Control	5.47 (4.13)	4.21 (4.62)	3.84 (4.61)	4.34 (4.13)	.036
Placebo	6.44 (2.70)	4.72 (4.31)	5.38 (4.18)	4.47 (4.18)	.009
Intervention	5.84 (4.21)	4.30 (4.35)	4.24 (4.27)	5.38 (5.69)	.008
			95% Wald Cl		
	В	SE	Lower	Upper	р
Intercept	4.05	0.99	2.11	5.99	.011
group Intervention	-0.16	1 1 2	-2.36	2.05	.891
		1.13			
Placebo Time	0.30	1.05	-1.77	2.36	.778
Week 3 (T ₃)	-1.20	0.81	-2.79	0.40	.141
Week 2 (T ₂)	-1.73	0.71	-3.12	-0.33	.015
Week 1 (T_1)	-1.27	0.53	-2.31	-0.22	.018
Group * Time	-1.27	0.55	-2.51	-0.22	.010
Intervention * T ₃	0.70	1.18	-1.61	3.01	.554
Intervention $* T_2$	0.05	1.03	-1.97	2.07	.959
Intervention T_1	-0.32	0.78	-1.84	1.21	.684
Placebo * T ₃	-0.81	1.13	-3.04	1.41	.474
					.545
Placebo * T ₂	0.60	0.99	-1.34	2.54	545

p < .05.

^b p < .01.

 c p < .001.PSQI = Pittsburgh Sleep Quality Index; ESS = Epworth Sleepiness Scale; SD = standard deviation; SE = standard error; CI = confidence interval.Outcome variables: PSQI score and ESS score. Covariates: stiffness, deformity, pain, fatigue, sleep medicine. A generalized estimating equation (GEE) model was used to test for differences between the intervention, placebo and control groups with respect to changes from baseline (T₀) to 1 week (T₁), 2 weeks (T₂), and 3 weeks (T₃) after adjusting for covariates. Reference group: control group * at baseline.

Table 3 shows that the ESS scores of the intervention group were significantly decreased from 5.84 (SD = 4.21) at baseline to 4.30 (SD = 4.35) at the first week, 4.24 (SD = 4.27) at the second week and to 5.38 (SD = 5.69) at the third week based on GEE analysis (p = .008). The ESS scores of the placebo group also statistically significantly decreased from 6.44 (SD = 2.70) at baseline to 4.72 (SD = 4.31) at the first week, to 5.38 (SD = 4.18) at the second week and 4.47 (SD = 4.18) at the third week (p = .009). The ESS scores of the control group also showed a statistically significant decrease from 5.47 (SD = 4.13) at baseline to 4.21 (SD = 4.62) at the first week, 3.84 (SD = 4.61) at the second week and 4.34 (SD = 4.13) at the third week. Compared with the control group,

both the patients in the intervention and placebo groups exhibited no statistically significant changes in ESS scores at all time points (Fig. 2). This result indicated that self-aromatherapy hand massage had no statistically significant effects on daytime sleepiness in patients with RA.

Discussion

This study aims to investigate the effects of self-aromatherapy hand massage on pain levels and sleep quality in patients with RA. Our study showed that 72.55% of the patients with RA reported pain, and 63.72% reported poor sleep quality, which was similar to a report from previous studies (Albayrak Gezer et al., 2017; Guo et al., 2016; Vergne-Salle et al., 2020). This indicates that pain and sleep quality are common problems in patients with RA and should be recognized by health care professionals, and individualized interventions should be provided. This study found that self-aromatherapy hand massage had statistically significant effects on the sleep quality of patients with RA after intervention. The PSQI and ESS scores of the intervention and placebo groups were significantly decreased from baseline to 3 weeks after selfaromatherapy hand massage. However, no statistically significant effects were found on the pain levels of patients with RA. Previous studies have reported inconsistent findings regarding the effects of aromatherapy on the pain levels of patients with RA or osteoarthritis (OA). This inconsistency might be attributed to the different forms of oils and doses applied to various regions (e.g., hand or knee) in different populations. Bahr et al. (2018) reported that aromatherapy massage using the AromaTouch Hand Technique® could decrease pain levels in 36 patients with RA/OA/chronic inflammation when treated with 50% v/v doTERRA Deep Blue® blend and 50% v/v dōTERRA Copaiba oil (intervention group) or 100% v/v dōTERRA Fractionated Coconut oil (control group) for 10 minutes twice daily for 5 consecutive days, but no statistically significant differences were found between the two groups.

Most previous studies administered aromatherapy massage to knee OA patients by using various oils, such as a 3-5% mixture including Lavandula Augustifolia and Rosmarinus officinalis, in base oils, such as coconut oil or almond oil, for 20-30 minutes, 3 times per week for 3-6 weeks (Efe Arslan et al., 2019; Gok Metin & Ozdemir, 2016; Nasiri et al., 2016; Tuna et al., 2018). These studies reported that aromatherapy massage was effective in decreasing pain levels in patients with knee OA. One explanation for the insignificant findings in our study was that the self-aromatherapy massage was administered by the participants themselves for only 10 minutes per session. Although the accuracy of the massage technique has been monitored by researchers with the teach-back method, more advanced training for participants is necessary. More frequent monitoring of patients' performance through visualized social media and telephone interviews is recommended. In addition, it is suggested that families be involved in the study to help with the performance of self-aromatherapy massage in future studies.

In this study, we used 5% compound essential oils (Cedarwood Atlas, Sweet Marjoram, Sweet Orange 3:1:1 in sweet almond oil) because these oils have anti-arthritic, pain relief, anti-inflammation and anxiety relief effects, as shown by a literature review and expert aromatherapist counselling. However, there is not enough previous evidence to support the effects of these oils on pain and sleep quality. Further studies are needed to evaluate the effects of these oils on pain and sleep quality in patients with RA. Additionally, each participant may have a different preference for oils, such as a favorite smell and familiarity with aromatherapy, which are based on previous experience and could also affect the acceptability and performance of aromatherapy massage. Thus, in the application of aromatherapy massage, the benefits or disadvantages of intervention should be considered, and these techniques should be tailored to the patients' individualized needs.

Limitations

Our study had several limitations. First, this study was conducted in one regional hospital, and the findings cannot be generalized to all patients with RA. Multicenter studies are suggested in future studies. Second, the self-aromatherapy massage was performed for only 10 minutes, 3 times per week, for 3 weeks. It is suggested to increase the dose of aromatherapy massage to 20-30 minutes, 3 times per week for 4-6 weeks, to assure the effects on pain levels. Third, this study used the NRS pain score to measure pain and self-reported scales for sleep quality. More objective measurements, such as electrical stimulators or actigraphy, are recommended for future studies.

Conclusions

Self-aromatherapy hand massage was effective in improving the sleep quality of patients with RA. The procedure is simple and easy to perform by the patients themselves at home; thus, it could be implemented as a complementary therapy for patients with RA. However, practitioners must consider the pros and cons of aromatherapy massage and tailor the interventions to the needs of patients with RA. In addition, more studies are needed to evaluate the effects of aromatherapy hand massage on the pain levels of patients with RA.

Clinical Implications

The 3-week self-aromatherapy hand massage technique is a simple and easy complementary therapy that can improve sleep quality in patients with rheumatoid arthritis. It is suggested that a self-aromatherapy hand massage program for patients with RA could be performed with a well-developed training course and frequent telephone follow-up monitoring, accompanied by guidance and instructions from a self- aromatherapy hand massage manual and video.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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