



“IMMEDIATE EFFECT OF COLD PACKS ALONG WITH STRETCHING OF CALF MUSCLE ON RESTLESS LEGS SYNDROME AND INSOMNIA IN PREMENSTRUAL SYNDROME AMONG YOUNG FEMALES.”

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Abstract: Premenstrual syndrome (PMS) is a common disorder occurring in females during their luteal phase of each menstrual cycle. RLS is a regular symptom occurring in PMS in addition to insomnia. The aim of study was to know the immediate effect of ice packs along with stretching of calf muscle in restless legs syndrome and insomnia in premenstrual syndrome. The study was conducted among 80 participants between the age 18 to 25 years. They were asked to fill the questionnaire before and after the treatment. The participants were given ice packs for 5 minutes over the calf accompanying stretching of calf muscle for three times with 30 seconds hold. The intra-group comparison showed a significant difference in the scores of PMSS, IRLSSG and Insomnia. According to the paired t-test, the value of p is less than 0.05. From the outcome of this study it was concluded that there is a positive effect of cold packs and stretching in the calf muscle for reducing RLS and Insomnia in individuals with PMS.

Index Terms- Premenstrual syndrome, Premenstrual syndrome scale, International Restless Legs Syndrome Study Group, Insomnia, ice packs, calf stretching.

INTRODUCTION

PMS is a frequent disorder that involves millions of women of reproductive age irrespective of socioeconomic status, race, or cultural background^[1,3]. Premenstrual syndrome (PMS) is specified as a cluster of physical and psychological symptoms that most women undergo during the late luteal phase of each menstrual cycle (8 to 10 days prior to menstruation)^[1,18]. Most of these symptoms vanish by their own with the beginning of follicular phase of the menstrual cycle^[2-3].

Premenstrual syndrome was first identified by a British physician Katharina Dalton in 1953^[8]. In the early period of the ancient Greeks, PMS psychological symptoms had been expressed, but it was recognized as a disorder by the medical community in 1931^[7]. There is a genetic predisposition of women whose mothers have a history of PMS are at a considerable risk of having this disease. Also 93% rate of PMS in monozygotic twins has a greater risk compared with 44% in dizygotic twins. Symptoms also vary with origin. A higher prevalence of food cravings is seen in Black women and prevalence of mood swings and weight gain is seen in the white women. Other risk factors like obesity and smoking have also been identified^[8]. Obese women are three times more likely to have PMS than non-obese women.

^[8] Women who smoke are more than two times likely to present with severe symptoms ^[8].

PMS has physical symptoms like leg pain, insomnia, mood swings, pain at pelvis, restless legs syndrome (RLS), appetite changes, emotional symptoms like anxiety, crying depression, irritability, behavior symptoms like forgetfulness, confusion ^[3]. When premenstrual syndrome occurs in severe form it is called Premenstrual dysphoric disorder (PMDD)^[12].

RLS is observed as a common neurological sensorimotor disorder that demonstrates an irresistible urge to move the body to reduce the uncomfortable sensations^[4]. The symptoms of the RLS was first reported by Willis in 1685 and then published by Swedish neurologist Ekbom in 1960, generally known as Willis- Ekbom syndrome^[4]. Despite being proposed a century ago, it's still a questioned disorder because of the unrevealed pathophysiology and relatively low morbidity, which results in repressed identification by primary care physicians and frequently under-diagnosed or misdiagnosed^[4]. There is a notable circadian rhythm of the RLS, which mostly worsens at night^[4].

Restless legs syndrome displays an immense urge to move the body to relieve the uncomfortable sensations, particularly when resting, sitting, or sleeping. The uncomfortable feelings are always described by the patients as “creeping, crawling, tingling, pulling, or painful” deep inside the limbs, unilaterally or bilaterally occurring with the knees, the ankles or even the whole lower limbs^[4].

A lot of time RLS affects the patient's sleep ^[4]. Sleeping is a programme when our body repairs tissue damage and works on integrating our memories in the brain^[20]. Insomnia is the frequent reason for a patient with RLS to search for consult in clinical practice^[4]. Difficulty in initiating sleep is the most regular bedtime problem caused by RLS^[4]. It follows a particular circadian pattern of intensifying symptoms in the evening and short suspension in the morning after waking up^[4]. Partial and temporary relief is there by doing movements such as walking, stretching, or bending the legs thus relieving the discomfort^[4]. Involuntary periodic limb movements during sleep (PLMS) is experienced approximately 80% of RLS patients that interrupts sleep. They are diagnosed by polysomnography^[6].

Epidemiology:

Almost 80–90% of women experience some symptoms in the premenstrual period in the course of their reproductive life. However, for PMS just 20% of these women satisfy the diagnostic criteria^[8]. As RLS is subjective and still under-reports its accurate prevalence, its exact number is still demanding. Rates are affected by various factors like age, by method of sampling, and by the criteria used to define the condition. Of the adult population, with ethnic variations it is estimated to affect between 3.9% and 14.3%^[5]. A study revealed that about 70% of the adult population is having insomnia once a month and 11% reporting unable to sleep every night^[20].

Making the Diagnosis:

According to the American College of Obstetricians and Gynecologists (ACOG) Clinical Management Guidelines, the key criteria for a diagnosis of PMS are:

(1) Symptoms consistent with PMS.

Consistent occurrence of the symptoms only during the luteal phase of the menstrual cycle.

(2) Negative impact of symptoms on some facet of the woman's life.

(3) Exclusion of other diagnoses that may better explain the symptoms^[6].

RLS is a subjectively defined disorder with diagnosis supporting the following criteria: (a) the wish to move that emerges during times of rest when sitting or lying down, and grows worse within the evening and within the dark and (b) uncomfortable sensations in the legs that are relieved by movement. RLS is diagnosed consistent with the International restless legs syndrome Study Group standardized criteria, which were last modified in 2014^[5].

Alternative therapies for PMS and RLS

PMS treatments have ranged from the dangerous ovarian irradiation to the theory of hiding in one's room. Recently, the focus on pharmacologic therapy has dominated the treatment for PMS^[6]. Clinical research now suggests that combination therapy is more beneficial than single treatment. New models of symptom management, which combine self-help, social support, medical therapies, and psychosocial strategies applied to specific conditions, have shown promising results^[6].

Various pharmacological medications are given over the period of time such as spironolactone, Ibuprofen, Iron oxide, Iron sulphate, Ropinirole, DHEC, and Pramipexole.^[7,8] The first line of treatment for RLS is either dopamine-receptor agonist or alpha 2 delta calcium channel ligand^[16]. Nowadays, non-pharmacological strategies are also implemented. Self-modification like increased consumption of complex carbohydrates, fruits, and vegetables, decreased use of salt, sugar, caffeine, and alcohol, increased water; small, frequent meals, Multivitamin/mineral supplements.

Self-regulations like behavioral therapy such as progressive muscle relaxation, imagery, and Breathing exercises, Cognitive strategies such as changing negative thought patterns, visualization, and self-esteem enhancement exercises. Environmental modifications like Training in time management, role redefinition, communication, and problem solving. Moreover, additional treatments including aerobic exercise, yoga, light therapy, massage are also developed^[6,9].

Yoga has advantageous effects over insomnia in PMS^[17]. Clinically acupuncture shows favorable results in the management of RLS^[19]. The Berries of shrub *Vitex agnus-castus* (agnus castus) is beneficial in treating premenstrual dysphoric disorder^[18].

METHODOLOGY

Study design: Experimental research Sampling: Convenience sampling

Study Setting: Physiotherapy department of Parul Sevashram hospital, Limda, Vadodara, Gujarat, India

Study Population: Young females (18 to 25 years) with PMS Study Duration: 6 months

Sample Size: 80 participants

SELECTION CRITERIA**Inclusion criteria:**

- 1) Discomfort in their legs that goes away by movement.
- 2) Continuous appearance of these symptoms before menstruation since 3 cycles.
- 3) The participant is between 18 years to 25 years of age experiencing PMS symptoms
- 4) The participant is between 18 years to 25 years of age.

Exclusion Criteria:

- 1) Leg discomfort is due to any other gynecological conditions or medications.
- 2) Consistent symptoms are not present before menstruation

Materials required:

- 1) Pen
- 2) Cold pack - The ice packs of measurement 5 inches x 18 inches were taken.
- 3) Assessment questionnaire: The assessment questionnaire was taken with the help of Google forms.
- 4) Consent Form

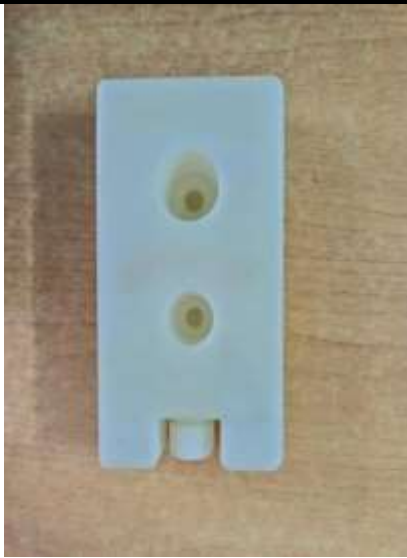


Figure 1: ICE PACK

TOOL USED:

- 1) Premenstrual syndrome scale (PMSS)
- 2) International Restless Legs Syndrome Study Group (IRLSSG) rating scale

PROCEDURE:

The Assessment Questionnaire was created with the help of the Premenstrual syndrome scale (PMSS) and International Restless Legs Syndrome Study Group (IRLSSG) rating scale which was used same as pre-treatment form and post-treatment form. Participants were selected if they fulfilled the inclusion criteria. Before signing the consent form the participants were told about their rights and responsibilities. As soon as they experienced RLS and insomnia before menstruation they were given treatment accordingly and review was taken through same questionnaire Google forms.

INTERVENTION:

Cryotherapy and manual stretching on calf muscle were given as treatments. All of the 80 participants were given the same protocol. Participants were initially instructed to fill the pre- assessment form and last menstruation date was also checked and then the treatment was given.

COLD PACK APPLICATION:

The patient was in prone lying and cold packs were applied on the calf muscle for 5 minutes on each leg. Then the patient was asked to change its position to supine.

MANUAL CALF STRETCHING:

Manual stretching was given for 3 times with 30 seconds hold after ice application over the calf muscle.

Hand Placement of Therapist: One hand was kept above the patella for stabilization and the other hand was at the plantar region of foot to stretch the muscle.

After the treatment the participants were asked to fill the post-assessment form and on this basis result were recorded and tabulated.



Figure 2: Ice pack over the calf muscle {5 minutes}



Figure 3: Manual Calf Stretching {3 times, 30 seconds Hold}

OUTCOME MEASURES:

The outcome measures taken in this study were PMSS and IRLSSG.

The PMSS scale was designed by Gençdoğan in Turkey. Premenstrual symptoms can be measured through this scale. Proper Validity and Reliability analyses were carried out extensively. The psychometric scale used is a Likert scale. On different age groups this scale has been utilized apart from high school and university students. [2] The inter-rater reliability result ranges from 0.81 to 0.97 as per the reports. Specificity range is 64-90% and sensitivity range is 83-100%^[10].

The IRLSSG rating scale was designed by clinical experts with this condition in accordance of questions suggested by representatives of the IRLSSG. An instrument was proposed by the International RLS Study Group (IRLSSG) and created a rating scale for measuring severity. It can be utilized for clinical practice, pathophysiological research, clinical trials and epidemiological research. High notable results of Reliability and Validity analyses suggest a quality standard for this instrument^[11].

Scoring:

The Assessment Questionnaire consisted of 19 questions with two subscales (Physiological symptoms and Psychological symptoms). The scoring was set according to the response

- “Never” or “None” as “0”,
- “Rarely” or “1 day a week or less” or “less than 1 hour per day” as “1”,
- “Sometimes” or “2 to 3 days a week” or “1 to 3 hours per day” as “2”,
- “Very Often” or “4 to 5 days a week” or “3 to 8 hours per day” as “3”,
- “Always” or “6 to 7 days a week” or “8 hours per day or more” as “4” points.

The lowest score achieved is “0” and the highest is “36” for PMSS scoring. The lowest score achieved is “0” and the highest is “40” for IRLSSG scoring.

Based on the total score, PMS is classified into “No Symptoms”, “Mild”, “Moderate”, “Severe”, “Very Severe”. As the score increases the severity of PMSS (Insomnia) and IRLSSG increases.

RESULT

80 participants were enrolled in the study. The statistical analysis was done with the help of Statistical Package for Social Sciences (SPSS; version 20) software. The significance level was set at 5% ($p=0.05$). Since the data was normally distributed, parametric tests were considered for intra-group comparison of PMSS, IRLSSG and Insomnia. For the statistical assessment paired sample t-tests were utilized.

Table 1: Table represents overview of PMSS, IRLSSG and Insomnia

	PRE-PMSS	POST-PMSS	PRE- IRLSSG	POST- IRLSSG	PRE- INSOMNIA	POST- INSOMNIA
Total	80	80	80	80	80	80
Mean	17.9750	10.6750	21.8875	12.6500	1.9750	1.1250
Median	18.0000	10.0000	22.0000	12.0000	2.0000	1.0000
Mode	18.00	7.00	20.00	12.00	2.00	1.00
Std. Deviation	5.79169	5.44193	6.60455	4.2041	1.16895	.86236

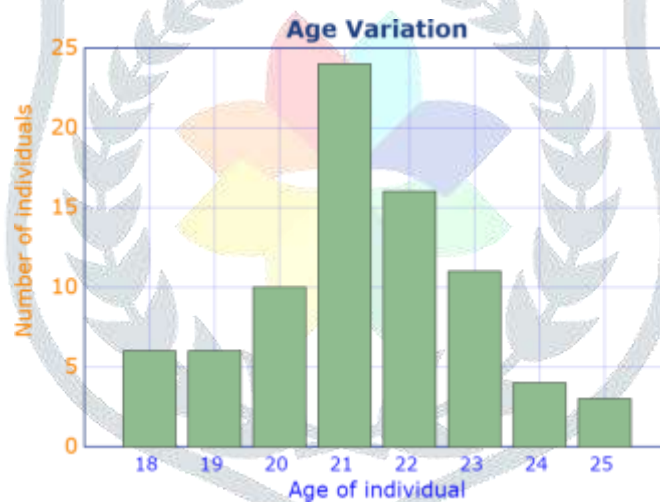
The overview of analysis of the intra-group is given in the Table 1, where mean, median, mode, standard deviation is described for before and after treatment for PMSS, IRLSSG and Insomnia.

AGE:

The young females taken were in the age group 18 to 25 years as shown in table. The graph1 also depicts the number of individuals present in the study.

Table 2: Table represents age variation of the study

AGE (in years)	NUMBER OF PARTICIPANTS
18	6
19	6
20	10
21	24
22	16
23	11
24	4
25	3



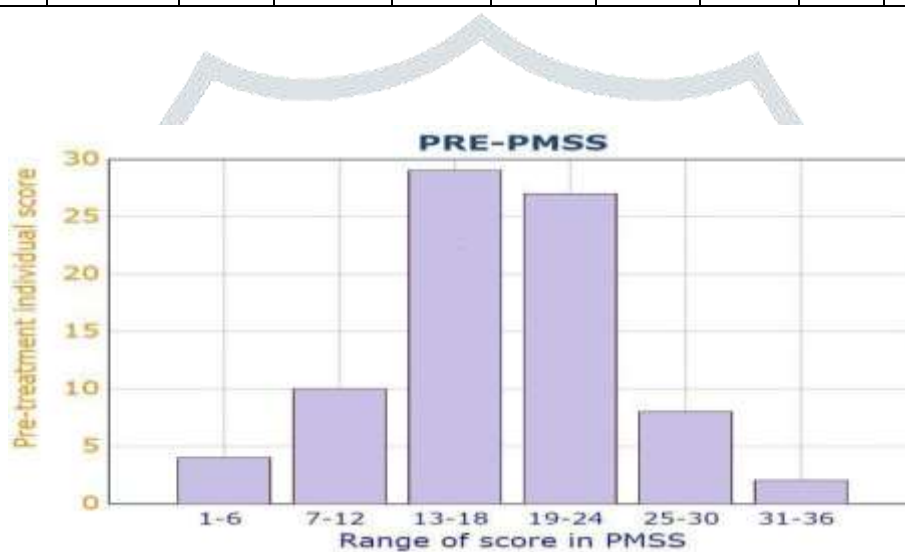
Graph 2: Graph represents Age of Participants

PMSS:

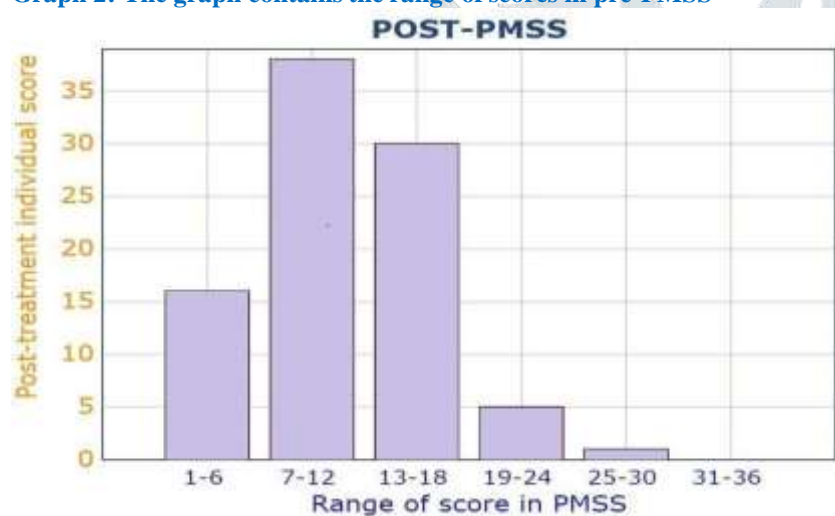
Comparison of pre-group and post-group results shows mean of 7.30 (SD = 5.26) and the t- value is 12.41 (p =0.0) shown in table 2. Differences between the scores are also given in graph 2 and 3.

Table 3 Table represents overview of PRE and POST PMSS

		Paired Differences					T	Df	Sig.(2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
PMSS	Pre&Post	7.3000	5.2612	.5882	6.1291	8.4708	12.41	79	.000



Graph 2: The graph contains the range of scores in pre-PMSS



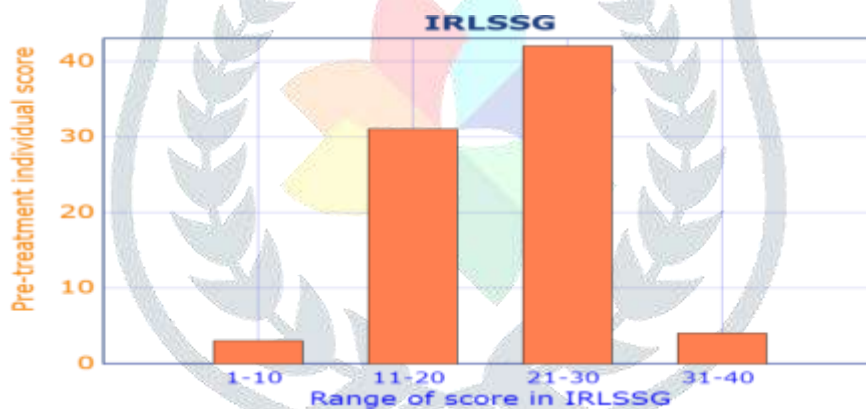
Graph 3: The graph contains the range of scores in post-PMSS

IRLSSG:

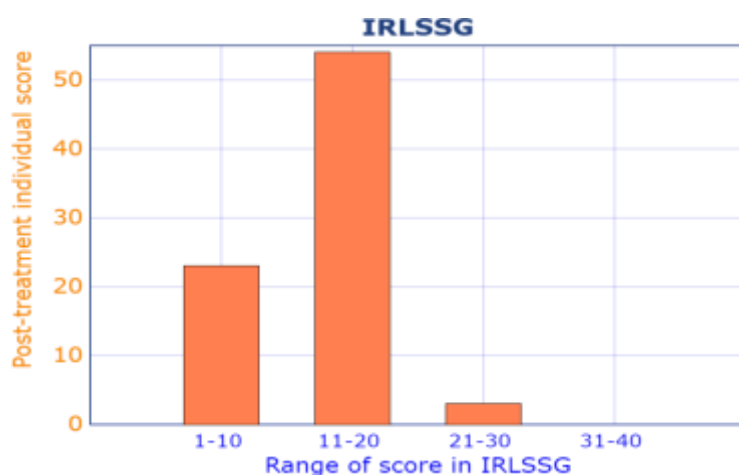
Results shows mean of 9.23 (SD = 5.01) of pre-group and post-group and the t-value is 16.47 (p =0.0) shown in table 3. Changes in the scores of pre-treatment and post-treatment are also given in graph 4 and 5.

Table 4: Table represents overview of PRE and POST IRLSSG

		Paired Differences					T	df	Sig.(2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
IRLSSG	Pre& Post	9.2375	5.01452	.56064	8.1215	10.3534	16.47	79	.000



Graph 4: The graph shows the range of scores in pre-IRLSSG



Graph 5: The graph shows the value of range of scores in post-IRLSSG

INSOMNIA:

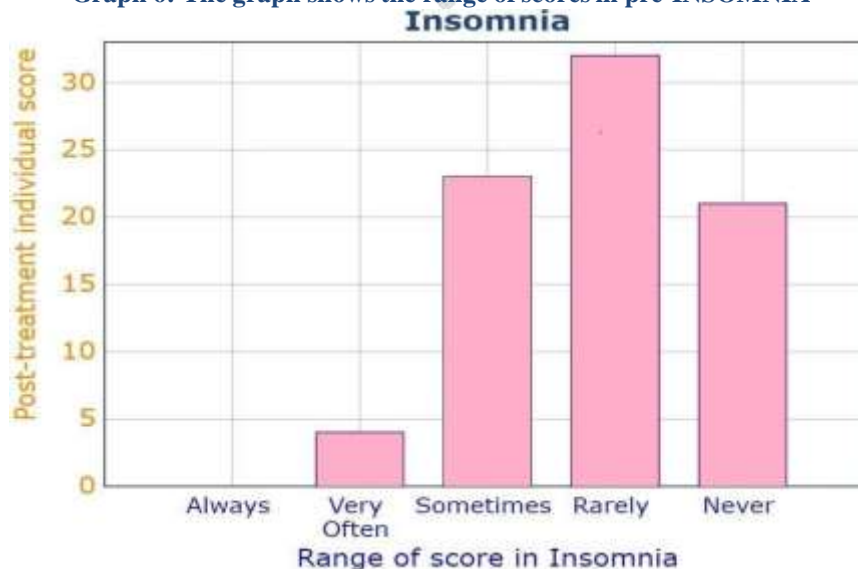
Difference between pre-group and post-group results shows mean of 0.85 (SD = 1.03) and thet-value is 7.36 (p =0.0) shown in table 4. The graph 6 and 7 shows the score obtained before and after the treatment.

Table 5 : Table represents overview of PRE and POST INSOMNIA

		Paired Differences					T	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Insomnia	Pre & Post	.85000	1.03239	.11542	.62025	1.07975	7.364	79	.000



Graph 6: The graph shows the range of scores in pre-INSOMNIA



Graph 7: The graphs shows the range of scores in post-INSOMNIA

DISCUSSION

The study was undertaken to know the efficacy of ice packs and stretching of calf muscle in Restless Legs Syndrome as well as in Insomnia during premenstrual period. The young females were taken as participants. Before the start of the treatment and in the end of the treatment participants were assessed.

The data suggests that there was a fall in the scores in PMSS from 17.97 to 10.67 (mean). This indicates that after the treatment little relief was obtained by the participants. In IRLSSG, a significant decrease was seen in the values from 21.88 to 12.65 (mean) specifying that restless legs syndrome have reduced in a good proportion. When compared to the Insomnia scores, a slight contrast was seen in the values from 1.97 to 1.12 (mean). This small difference describes that insomnia was brought down to a minimum amount.

EFFECTS OF ICE PACKS IN RLS AND INSOMNIA

Application of ice pack would result in immediate vasoconstriction of blood vessels which triggers the thermal receptors in the skin following vasodilatation after few minutes then again results in vasoconstriction.

Cryotherapy follows the principle of Lewis Hunting Reaction. This leads to decrease in cellular metabolism, reducing pain and spasm^[23]. Monali Tanna (2019) conducted a comparative study which stated that cryotherapy along with stretching for calf cramps is more effective in antenatal women. Cryotherapy provides analgesic effects which minimize the effect of RLS. As insomnia is a comorbid symptom of RLS, decreasing the severity of RLS would result in decreasing insomnia periods.

EFFECTS OF STRETCHING IN RLS AND INSOMNIA

The present study shows reduction in RLS symptoms after the intervention. Joannes and colleagues (2012) conducted an experimental research that stretching of calf and hamstring significantly reduces the frequency and severity of nocturnal leg cramps in older people.

There is activation of antagonist muscles, when stretching in the muscle is initiated during the cramps. Stretching of muscle causes immediate interruption of cramps by voluntary contraction. This passive stretching activates autogenic inhibitory Ib afferents in the respective tendon. There is a proposal that group III tendon afferents inhibits the terminals of Ia stretch reflex afferents presynaptically which are responsible for inhibition of cramps. Thus, lengthening of muscle helps to inhibit the course and development of cramp^[14].

In 2018, Carolina and colleagues conducted a study on effects of resistance exercise training and stretching on chronic insomnia. They concluded that stretching helps in decreasing the severity of insomnia^[21]. There are tension-reducing effects of stretching which assists in reduction of insomnia.

The result indicates that there is a positive effect of cold packs and stretching in RLS and Insomnia in PMS

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