

# An Open Label Comparative Clinical Study on *Virechana Karma* and *Patra Pinda Sweda* followed by *Vishwadi Dwadashanga Kwatha* in the Management of *Mamsagata Vata* w.s.r to Fibromyalgia

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**Abstract:** Background: Fibromyalgia is a chronic pain disorder characterized by widespread musculoskeletal pain, fatigue, and tenderness, often accompanied by sleep disturbances, cognitive dysfunction, and mood disorders. Conventional treatments primarily focus on symptom management, often yielding suboptimal outcomes. Ayurveda correlates fibromyalgia with Mamsagata Vata, involving Vata dosha vitiation in muscular tissues (Mamsa dhatu), causing pain, stiffness, and functional impairment. Ayurveda management aims to restore dosha balance and enhance tissue health through holistic therapies. Virechana Karma (therapeutic purgation) detoxifies the body, targeting Pitta and Vata dosha, and reduces inflammation. Patra Pinda Sweda (herbal leaf bolus fomentation) alleviates pain and stiffness by improving circulation and relaxing muscles. Vishwadi Dwadashanga Kwatha, a herbal decoction, provides analgesic, anti-inflammatory, and Vata-pacifying benefits, supporting long-term relief from musculoskeletal disorders. This study aims to evaluate the comparative effectiveness of Virechana Karma and Patra Pinda Sweda followed by Vishwadi Dwadashanga Kwatha in managing Mamsagata Vata, with a focus on fibromyalgia. Integrating purification, external therapies, and internal medication, the research seeks to provide an evidence-based, holistic approach to managing this complex condition. Objective: The Primary aim is To compare the effect of Virechana Karma and Patra Pinda Sweda Followed by Viswadi Dwadashanga Kwatha in the management of Mamsagata Vata with special reference to Fibromyalgia. Methods: This ongoing study is an open-label randomized comparative interventional trial, with a sample size of 78 both in the trial and standard control group (including dropouts, 10%). Participants in the trial group will receive Virechana Karma. Followed by Viswadi Dwadashanga Kwatha 20 GM BD (Morning and evening before meal) with Luke warm water for a period of fifteen days. The participants in the control group will receive Patra Pinda Sweda followed by Viswadi Dwadashanga Kwatha 20 GM BD (Morning and evening before meal) with Luke warm water for 15days. Outcome Measures: The primary outcome will include the mean change & improvement present in Mamsagata Vata symptoms of registered patients, improvement and change present symptoms in fibromyalgia. The secondary outcomes will include the Changes in FIBROMYALGIA IMPACT QUESTIONNAIRE (FIQ). Ethics: Ethics approval was taken from the Institutional Ethics Committee following which recruitment will be commenced in January 2025.

**Clinical Trial Registration:** CTRI/2024/08/072730 dated 20.08.2024

**Keywords:** Mamsagata vata, Fibromyalgia, Vishwadi dwadashanga kwatha, Patra pinda sweda, virechana karma

## 1. Introduction

Pain with destructive and demoralizing effects remains a challenging problem for both patients and caregiver, Fibromyalgia syndrome (FMS) is defined as a chronic pain syndrome with a complex, multifactorial and not completely known etiopathogenesis and an increased frequency among women. Fibromyalgia is most common pain disorders after only to osteoarthritis seen in rheumatology practices. It is characterized by generalized musculoskeletal pain and palpation specific tender points on physical examination often accompanied by associated symptoms such as sleep disorders, fatigue, somatic and cognitive symptoms, as well as psychic disorders. Due to this fibromyalgia is a debilitating disorder that has negative effect on patient's quality of life and thus impairing the patient's day to day activities. Disturbed sleep has been implicated as a factor in the pathogenesis. Other risk factors include life events that cause psychosocial distress such as marital disunity, injury assault, alcoholism in the family, low income and child

abuse<sup>[1]</sup>.

The cause, etiology, and pathophysiology of Fibromyalgia are still unclear; a few hypotheses have been developed including central sensitization. This theory recommends that FMS patients have a lower threshold for pain due to increased reactivity of pain sensitive nerve cells in the spinal cord or brain. Recent FMS guidelines therefore suggests a multimodal multidisciplinary therapeutic approach including medication, exercise, patient's education and behavioral and psychosomatic therapies. Because of frequent unsatisfying results of conventional medicine (CoM) treatment a substantial proportion of patients use complementary and integrative approaches such as nutritional supplements, phytotherapy, acupuncture, massage, various nutritional therapies, and traditional and whole medical systems (WMS) *Ayurveda* <sup>[2]</sup>. The first ever description of the disease multiple and widespread pain in muscles ultimately fatigue in *Ayurveda* text was mentioned as *Mamsagata Vata*<sup>[3]</sup>. The specific disease condition

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associated with *Gurvang*, *atyarth todanvat vedana*, *Dandmushtihatamvedana*, *tatha atyarth sharmita*<sup>[4]</sup>. (Multiple and widespread pain in muscles ultimately fatigue, palpation specific tender points accompanied with associate symptom such as sleep disorders, somatic and cognitive symptoms as well as psychic disorders)<sup>(5)</sup>.

The textual line of treatment of *Vatavyadhi* is followed in the treatment of *Mamsagata Vata* which states *Virechana*, *Niruha Basti* and *Shaman Chikitsa*<sup>[6]</sup>. Present scenario is the era of integration, each of the medical science is looking at each other as a complementary to its branch which can support its own short comings. External *snehana* and *swedana* have been recommended to alleviate symptoms such as *toda* (pain), *harsha* (tingling feeling), *ruka* (tenderness), *Sotha* (oedema), *stambha* (stiffness), and *anga graham* (sprain). Because *Mamsagatavata* (fibromyalgia) a share many symptoms, it can be used as a therapy option there.<sup>[7]</sup> So, with the same thought the present work is planned. In this work *Virechana* and *patra pinda sweda* followed by *Vishwadi Dwadashanga Kwatha* are purposed as an adjuvant therapy.

## 2. Need of the Study

Fibromyalgia prevalence on a global rate range between 0.7 to 3.3% in adult population with an increase in recent years and a continuous trend towards female patients.<sup>[8]</sup> The modern medicine having limitation and certain side effect such as nausea, fatigue, dry mouth, blurred vision, weight gain, swelling of hands and feet, etc.<sup>[9]</sup> Thus because of lots of side effects *Ayurveda* is answer to this problem in the manner of *Shodhana* and *Shamana Chikitsa*. It is safer medicine for *Vata Vyadhi*. *Virechana*, *Niruha Basti* & *Shamana Chikitsa* are the chiefly advocated *Panchakarma* procedure for *Mamsagata Vata*.<sup>[10]</sup> Therefore, there is need of study to rule out the effective, safer, and economical methods for the management of '*Mamsagata Vata*. There is also need to evaluate the efficacy of *Shodhana Karma* based on the predominance of *Dosha* for the better management of diseases. Thus, an effort is made to evaluate *Virechana Karma*, and *Patra pinda Sweda* followed by *Vishwadi Dwadashanga Kwath* is more effective in management of *Mamsagatavata* with special reference to Fibromyalgia. There is need of a therapy that can provide substantial relief in Fibromyalgia. There is need of adjuvant therapy that can be in harmony with any medical system. Studies are needed to enrich principle-based *Ayurveda* treatments.

### Hypothesis

#### Research Hypothesis

There is effect of *Virechana Karma* and *Patra Pinda Sweda Vishwadi Dwadasanga Kwatha* in the management of *Mamsagata Vata* with special reference to Fibromyalgia.

#### Null Hypothesis

There is no effect of *Virechana Karma* and *Patra Pinda Sweda Vishwadi Dwadasanga Kwatha* in the management of *Mamsagata Vata* with special reference to Fibromyalgia.

## 3. Review of Literature

### A. Historical Review: -

The most-often cited historical account of fibromyalgia comes from a 2004 paper by researchers Fatma Iannucci and Muhammad B. Yunus. This history was compiled from their work as well as new information from the past decade. Early on, doctors didn't have separate definitions for all the pain conditions we recognize today.

Descriptions and terminology started out broad and gradually were narrowed down. In 1592, French physician Guillaume de Baillou introduced the term "rheumatism" to describe musculoskeletal pain that didn't originate from injury. This was a broad term that would have included fibromyalgia as well as arthritis and many other illnesses. Eventually, doctors began to use "muscular rheumatism" for painful conditions that, like fibromyalgia, didn't cause deformity. Two-hundred years later, definitions still were rather vague. However, in 1815, Scottish surgeon William Balfour noted nodules on connective tissues and theorized that inflammation could be behind both the nodules and pain. He was also the first to describe tender points (which would later be used to Diagnose fibromyalgia). A few decades later, French doctor, Francios Valleix, used the term "neuralgia" to describe what he believed was referred pain from tender points traveling along the nerves. Other theories of the day included hyperactive nerve endings or problems with the muscles themselves. In 1880, American neurologist George William Beard coined the terms neurasthenia and myasthenia to describe widespread pain along with fatigue and psychological disturbance. He believed the condition was caused by stress.<sup>[11]</sup>

### Ayurved Review (Disease): -

The first ever description of the disease multiple and widespread pain in muscles ultimately fatigue in *Ayurveda* text was mentioned as *Mamsagata Vata*<sup>[12]</sup>. The specific disease condition associated with *Gurvang* (heaviness in the body), *Atyarth Todanvat Vedana* (prinking pain in the body), *Dandmushtihatam Vedana* (pain like stick hitting), *Tatha Atyarth Sharmita* (fatigability)<sup>[13]</sup>. Multiple and widespread pain in muscles ultimately fatigue, palpation specific tender points accompanied with associate symptom such as sleep disorders, somatic and cognitive symptoms as well as psychic disorders.<sup>[14]</sup>

### Modern Review: -

Pain with its devastating and demoralizing effects remains a challenging problem for both patients and care givers.<sup>[15]</sup> Fibromyalgia is one of the most common diseases affecting the muscles manifested with pain, stiffness, and tenderness of the muscles, tendons, and joints. The painful tissues involved are not accompanied by tissue inflammation.<sup>[16]</sup><sup>[17]</sup> Therefore, despite potentially disabling body pain; patients with fibromyalgia do not develop tissue damage or deformity.<sup>[18]</sup><sup>[19]</sup> The pain of fibromyalgia is generally widespread, involving both sides of the body. Pain usually affects the neck, buttocks, shoulders, arms, the upper back, and the chest. "Tender points" are localized tender areas of the body that can bring on widespread pain and muscle spasm when touched.<sup>[20]</sup><sup>[21]</sup>

FMS typically presents in young or middle-aged females as persistent widespread pain, stiffness, fatigue, disrupted unrefreshing sleep, and cognitive difficulties, often accompanied by multiple other unexplained symptoms, anxiety or depression, and functional impairment of daily living activities. [22] [23] There is an overall 6% to 15% prevalence rate in the United States with a five times greater incidence among women than men. In rheumatology clinics, the rate of new diagnosis is approximately 10% to 20%, where as in non-specialized settings, the rate is 2.1% to 5.7%. [24][25]

Clinicians should be familiar with the signs and symptoms

of fibromyalgia and diagnose the condition with minimum investigation. [26] Since the symptoms of fibromyalgia wax and wane related to stresses, [27] treatment (as with that of other chronic diseases) is an ongoing process rather than management of a single episode.

In terms of conditions associated with fibromyalgia; there are certain conditions associated with fibromyalgia.

#### Drug Review:

#### Drugs of Trivrit Leha-(Charak samhita Kalpsthana, 7/24-25) [28]

S. No.	Drug Name	Botanical Name	Part Used	Ratio
1.	Trivrit Kwath	Decoction of <i>Operculina turpethum (L.) Silva Manso</i>	Stem	2
2.	Sugar	<i>Saccharum officinarum Linn</i>	-	2
3.	Trivrit Churna	Powder of <i>Operculina turpethum (L.) Silva Manso</i>	Stem	1
4.	Honey	<i>Mal depuratum</i>	-	1
5.	Twak	<i>Cinnamomum zeylanicum Beryn.</i>	Barks	1/24
6.	Tamalpatra	<i>Cinnamomum tamala Nees and Eberm</i>	Leaf	1/24
7.	Marich	<i>Piper Nigrum Linn.</i>	Fruits	1/24

#### Drugs of Patra Pinda Sweda:-

शिशु चिंचा अर्क निर्गुण्डि वरण एरण्ड पल्लवैः।अन्यैर्वा तत्  
समैः स्वित्नेः तैलस्वित्रैः स केरकैः॥  
कार्पास पिण्डिका कृत्वा ताभिः तप्तभिर् एव वा।स स्नेहपात्रे  
संतप्ते निक्षिप्ताभः मुहःमुहः॥  
(Arogya kalpa druma) [29]

S.n.	Drugs	Botanical	Part use	Ratio
1.	Nirgundi	<i>Vitex negundo</i>	leaves	100 gm
2.	Eranda	<i>Ricinus communis</i>	leaves	100 gm
3.	Chincha	<i>Tamarindus indica</i>	leaves	100gm
4.	Datura	<i>Datura metel</i>	leaves	25gm
5.	Shigru	<i>Moringa oleifera</i>	Leaves	25 gm
6.	Arka	<i>Calotropis procera</i>	Leaves	25 gm
7.	Narikela	<i>Cocus nucifera</i>	Fruit	150 gm
8.	Nimbuka	<i>Citrus lemon</i>	Fruit	100 gm
9.	Til tail	<i>Sesamum indicum</i>	Seeds	100ml

#### Drugs- Viswadi Dwadashanga Kwatha – (Bharat Bhaishjya RatnakarYog no.6543) [30]

S. No.	Drug	Botanical Name	Part used	Ratio
1	Viswabhaishajya	<i>Zingiber officinale</i>	Rhizome	1
2	Eranda	<i>Ricinus communis</i>	Leaves,root	1
3	Devdaru	<i>Cedrus deodara</i>	Bark	1
4	Vacha	<i>Acorus calamus</i>	Root	1
5	Shunti	<i>Zingiber officinale</i>	Rhizome	1
6	Duralabha	<i>Fagonia cretica</i>	Whole plant	1
7	Abhaya	<i>Termanalia chebulla</i>	Fruit	1
8	Aivisha	<i>Aconitum heterophyllum</i>	Root tubers	1
9	Musta	<i>Cyperus rotandus</i>	Tuber	1
10	Shatavari	<i>Asperagus racemosus</i>	Root	1
11	Vasa	<i>Adhatoda vasica</i>	leaves	1
12	Amrita	<i>Tinospora cordifolia</i>	Stem	1

#### Aim of study:

- To compare the effect of *Virechana Karma* and *Patra Pinda Sweda* Followed by *Viswadi Dwadashanga*

*Kwatha* in the management of *Mamsagata Vata* with special reference to Fibromyalgia.

#### Primary Objective:

- To evaluate the effect of *Virechana Karma* and *Patra Pinda Sweda* Followed by *Viswadi Dwadashanga Kwatha* in the management of *Mamsagata Vata* with specialreference to Fibromyalgia

#### Secondary Objective:

To compare the effect of *Virechana Karma* and *Patra Pinda Sweda* Followed by *Viswadi Dwadashanga Kwatha* in the management of *Mamsagata Vata* with special reference to Fibromyalgia

#### Research Design:

#### Clinical Study:

#### Source of Data-

- Participants-** OPD & IPD of Shri Shirdi Sai Baba Ayurvedic College & Hospital Mundiagarh, Kishangarh, Renwal
- Clinical Source – CRF (Case Report Form)
- Literary Source** – *Ayurvedic* Texts, Research articles, thesis, papers
- Study Type:** Interventional, open, Randomized, Single centric, Clinical, Comparative study.
- Purpose:** Treatment
- Allocation:** Randomized
- Masking:** Open
- Assignment:** Parallel assignment with Randomization
- Timing:** Prospective
- End Point:** Efficacy Study
- Participants:** 78 (39 each group)
- Total periods of study-** 45 days/ patient

#### Diagnostic criteria

#### Criteria of diagnosis –

The diagnosis is made based on sign and symptoms of the

patients.

#### Inclusion Criteria

- Patients between 18 and 60 years of age.
- Patients with the clinical features of *Mamsagata Vata*.
- Patients with the clinical features of Fibromyalgia.
- Patients fit for *Virechana Karma*.
- Chronicity less than 10 years
- FIQ Score should be < 33.

#### Exclusion Criteria

- Patient, suffering from any chronic debilitating disease like T.B., Varicose vein, Asthma, Rheumatoid Arthritis & other chronic problems etc. and having other serious pathology.
- Patients suffering from systemic disorders as cardiac problem, Diabetes Mellitus, Hypertension more than 140mmHg Systolic pressure & diastolic pressure more than 90 mmHg, Paralysis, Malignancy, HIV, HBsAg, Leprosy.
- Pregnant women and lactating mother.

#### Criteria for withdrawal –

- During the course of trial, if any serious condition or any serious adverse effects which require urgent treatment or if patient himself want to withdraw from trial.

#### Sample size calculation:

- 78 Patients (39 patients each group)

#### Sample size:

- In this study the sample size is taken as 39 patients in each group. All the patients willing to participate and eligible for the study will be included in trial.

**Name and place study where conduct:** -Shri Shirdi Sai Baba Ayurvedic College & Hospital Mundiagarh, Kishangarh, Renwal

#### Assessment criteria:

- The assessment of the clinical response in the total number of patients will be made on Subjective Parameters like Sign and symptoms, FIQ, VAS score and Objective Parameters.

#### Primary outcome

- Any change & improvement present in *Mamsagata Vata* symptoms of registered patients
- Improvement and change present symptoms in fibromyalgia.
- Changes in FIBROMYALGIA IMPACT QUESTIONNAIRE (FIQ) <sup>[31]</sup>

#### VAS-Scale:

VAS have been recommended: no pain (0–4 mm), mild pain (5–44 mm), moderate pain (45–74 mm), and severe pain (75–100 mm) <sup>[32]</sup>

#### Randomization –

Patient will be randomized by the predesigned randomization schedule using Research Randomizer.

#### Subjective Parameters <sup>[33]</sup>

##### *Gaurvham* (heaviness in the body)

1	Absent	0
2	Occasional	1
3	Frequently	2
4	Regularly	3

##### *Todvadvedana* (prinking pain in the body)

1	No prinking pain	0
2	Mild prinking pain	1
3	Moderate prinking pain	2
4	Severe prinking pain	3

##### *Dand musthiat Vedana* (pain like stick hitting)

1	No pain like stick hitting	0
2	Mild pain like stick hitting	1
3	Moderate pain like stick hitting	2
4	Severe pain like stick hitting	3

##### *Atisharma*(fatiguability)

1	Can do routine exercise / work	0
2	Can do moderate exercise with hesitancy	1
3	Can do mild exercise only, with difficulty	2
4	Cannot do mild exercise too	3

##### *Granthi*(nodule) ( su.nid.1/26)

1	Absent	0
2	1-2 nodule present	1
3	3-5 nodule present	2
4	> 5 nodule present	3

#### Part 1: Widespread Pain Index

##### Calculate the patient's Widespread Pain Index (WPI)

- 1) Using the list of 19 body areas, identify the areas where the patient felt pain over the past week. As a visual aid, front/back body diagrams are included. — Each area identified on the list counts as 1
- 2) Total the number of body areas (the WPI score can range from 0 to 19).

Write the patient's WPI score here: .....

##### Identify the areas where the patient felt pain over the past week:

Shoulder girdle, left	Lower arm, right	Lower leg, left	Abdomen
Shoulder girdle, right	Hip (buttock), left	Lower leg, right	Neck
Upper arm, left	Hip (buttock), right	Jaw, left	Upper back
Upper arm, right	Upper leg, left	Jaw, right	Lower back
Lower arm, left	Upper leg, right	Chest	

##### Part 2a: Symptom Severity Scale (Levels of Severity)

The patient's level of symptom severity is measured as below.

- 1) Using a scale of 0 to 3, indicate the patient's level of symptom severity over the past week in each of the 3 symptom categories— The score is the sum of the numbers that correspond to the severity levels



identified in all 3 categories.

write the number here:

2) Total the scale numbers for all the 3 categories and

Fatigue	Walking unrefreshed	Cognitive symptoms
0= No Problem	0= No Problem	0= No Problem
1= Slight or mild problems; generally mild or intermittent	1= Slight or mild problems; generally mild or intermittent	1= Slight or mild problems; generally mild or intermittent
2= Moderate; considerable problems; often present and/ or at a moderate level	2= Moderate; considerable problems; often present and/ or at a moderate level	2= Moderate; considerable problems; often present and/ or at a moderate level
3= Severe; pervasive, continuous, life-disturbing problems	3= Severe; pervasive, continuous, life-disturbing problems	3= Severe; pervasive, continuous, life-disturbing problems

**Part 2b: Symptom Severity Scale (Other SOMATIC SYMPTOMS) Determine the extent of the patient’s other Somatic Symptoms**

Using the symptoms list on the following page, determine the extent of other somatic symptoms the patient may have experienced over the past week.

- 1) Determine the quantity of somatic symptoms using the list on the following page.
- 2) Using your best judgment, calculate the score that matches the quantity of those somatic symptoms and write the number here:

**Add the scores from Parts 2a and 2b (the Symptom Severity score, or SS score, can range from 0 to 12).**

**Write the patient’s SS score here: .....**

Based on the quantity of symptoms, the patient’s score is:

- 1) 0 = No symptoms
- 2) 1 = Few symptoms
- 3) 2 = A moderate number of symptoms
- 4) 3 = A great deal of symptoms

**The Patient’s Score Means**

The patient’s WPI score (Part 1)

.....

The patient’s SS score (Parts 2a and 2b)

.....

**A patient meets the diagnostic criteria for Fibromyalgia if the following 3 conditions are met:**

- 1) 1a. The WPI score (Part 1) is greater than or equal to 7

Were you able to	Always	Most	Occasionally	Never
1. Do shopping?	0	1	2	3
2. Do laundry with a washer and dryer?	0	1	2	3
3. Prepare meals?	0	1	2	3
4. Wash dishes/cooking utensils by hand?	0	1	2	3
5. Vacuum a rug?	0	1	2	3
6. Make beds?	0	1	2	3
7. Walk several blocks?	0	1	2	3
8. Visit friends or relatives?	0	1	2	3
9. Do yard work?	0	1	2	3
10. Drive a car?	0	1	2	3
11. Climb stairs?	0	1	2	3

Of the 7 days in the past week, how many days did you feel good?

0 1 2 3 4 5 6 7

How many days last week did you miss work, including housework, because of fibromyalgia?

0 1 2 3 4 5 6 7

For the remaining items, mark the point on the line that best indicates how you felt overall for the past week.

and the SS score (Parts 2a and 2b) is greater than or equal to 5. OR 1b. The WPI score (Part 1) is from 3 to 6 and the SS score (Parts 2a and 2b) is greater than or equal to 9.

- 2) Symptoms have been present at a similar level for at least 3 months.

**The patient does not have a disorder that would otherwise explain the pain.**<sup>[34]</sup>

**Objective Parameters: -**

Laboratory Investigations should be done before and after treatment –

To exclude the other disease conditions and diagnosis purpose – ESR, HB, TLC, DLC, CRP, RA Factor, Thyroid stimulating hormone, Liver function test and Kidney function test.<sup>[35]</sup>

- 1) **Fibromyalgia Impact Questionnaire (FIQ)** - Burckhardt C.S, Clarck, S, R & Bennett, RM (1991), The Fibromyalgia Impact Questionnaire: Development and Validation. Journal of Rheumatology, 18, 728-734

**Directions:** For questions 1 through 11, please circle the number that best describes how you did overall for the past week. If you don't normally do something that is asked

**When you worked, how much did pain or other symptoms of your fibromyalgia interfere with your ability to do your work, including housework?**

No problem with work • I I I I I I I I I I • Great difficulty with work

**How bad has your pain been?**

No pain • I I I I I I I I I I • Very severe pain

**How tired have you been?**

No tiredness • I I I I I I I I I I • Very tired

**How have you felt when you get up in the morning?**

Awoke well rested • I I I I I I I I I I • Awoke very tired

**How bad has your stiffness been?**

No stiffness • I I I I I I I I I I • Very stiff

**How nervous or anxious have you felt?**

Not anxious • I I I I I I I I I I • Very anxious

**How depressed or blue have you felt?**

Not depressed • I I I I I I I I I I • Very depressed

**Scoring-** the FIQ is scored in such a way that a higher score indicates a greater impact of the syndrome on the person. Each of the 10 items has a maximum possible score of 10. Thus, the maximum possible score is 100. The average FM patient scores about 50, severely afflicted patients are usually 70 plus. The questionnaire is scored in the following manner:

The first item consists of 11 questions that make up a physical functioning scale. The 11 questions are scored and summed to yield one physical impairment score. Each item is rated on a 4-point Likert type scale. Raw scores on each item can range from 0 (always) to 3 (never) - thus, the highest total possible raw score is 33. Because some patients may not do some of the tasks listed, they are given the option of deleting items from scoring. In order to obtain a valid summed score for questions 1 through 11, the scores for the items that the patient has rated are summed and divided by the number of items rated (e.g., if the patient completed only 9 items at a score of 2 for each, the final score would be  $9 \times 2 / 9 = 2$ ). An average raw score between 0 and 3 is obtained in this manner.

Item 2 is scored inversely - so that a higher number indicates impairment (i.e., 0=7, 1=6, 2=5, 3=4, 4=3, 5=2, 6=1 and 7=0, etc.). Raw scores can range from 0 to 7.

Item 3 is scored directly (i.e., 7=7 and 0=0). Raw scores can range from 0 to 7. Items 4 through 10 are scored in 10 increments. Raw scores can range from 0 to

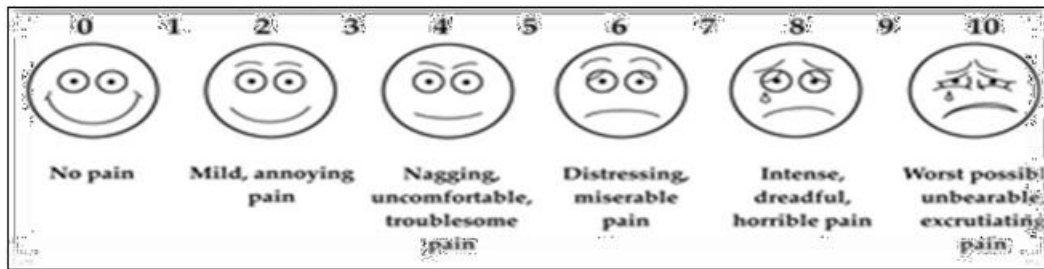
If the patient marks the space between two vertical lines on any item, that item is given a score that includes 0.5.

Once the initial scoring has been completed, the resulting scores are subjected to a normalization procedure so that all scores are expressed in similar units. The range of normalized scores is 0 to 10 with 0 indicating no impairment and 10 indicating Maximum impairment.

Scale	Item	Recode	Score Range	Normalization
Physical Impairment	1	No	0-3	S X 3.33
Feel good	2	Yes	0-7	S X 1.43
Work missed	3	No	0-7	S X 1.43
Do work	4	No	0-10	None
Pain	5	No	0-10	None
Fatigue	6	No	0-10	None
Rested	7	No	0-10	None
Stiffness	8	No	0-10	None
Anxiety	9	No	0-10	None
Depression	10	No	0-10	None

**Note-** In order to maintain a maximum possible score of 100 it is necessary to employ an-equalization calculation if a patient does not answer all 10 items. If one or more items are missed, the final summative score needs to be multiplied by 10/x. (e.g., if one question is missed multiply by 10/9 [i.e. 1.111], if 2 questions are missed multiply by 10/8 [36].

**VAS – Scale:  
Scoring and Interpretation:**



- Using a ruler, the score is determined by measuring the distance (mm) on the 10-cm line between the “no pain” anchor and the patient’s mark, providing a range of scores from 0–100.
- A higher score indicates greater pain intensity. Based on the distribution of pain VAS scores in post-surgical patients (knee replacement, hysterectomy) who described their post operative pain intensity as none, mild, moderate, or severe, the following cut points on the pain VAS have been recommended: no pain (0–4 mm), mild pain (5–44 mm), moderate pain (45–74 mm), and severe pain (75–100 mm)

### Grouping

Patients will be randomly divided into two groups (39 patients in each group) detail as below-

**Group A** – *Virechana Karma*. Followed by *Viswadi Dwadashanga Kwatha*

**Group B** – *Patra Pinda Sweda* followed by *Viswadi Dwadashanga Kwatha*

### Route and method of application –

- 1) *Virechana* will be conducted as per standard protocol and *Virechana Yoga* will be given according to *Koshtha* on empty stomach at 9-10 am.
- 2) *Patra Pinda Sweda* will be carried out in accordance with standard procedure for a 15-day for local application.
- 3) *Viswadi Dwadashanga Kwatha* as *Shamana Chikitsa* for 15 days.

**Time of administration of *Virechana Karma*** – Late morning, Panchkarma Department Shri Shirdi Sai Baba Ayurvedic College & Hospital Mundiagarh, Kishangarh

,Renwal

### Route and method of administration of *Virechana Karma* –

- *Deepan Pachan - Gandhak vati* 2tab bd for 5 days.
- *Snehpana* –It will be done by *Go-Grhita* for 3 to 7 days
- *Sarvanga Abhyanga* (with *Dashmoola Taila*)  
*Sarvanga Swedana* (with *Dashmoola Kwatha*) for continue 4 days.
- *Virechana* will be conducted as per standard protocol and *Virechana Yoga* will be given through Oral route according to *Koshtha* on empty stomach at 9-10 am.
- *Sansarjana Krama* - According to *Shuddhi*.

**Patra Pinda Sweda preparation:** - Fresh leaves should be cleaned and chopped finely. First add 50 ml of prescribed oil into frying pan, to this add grated coconut & sliced lemon and fry till it turns to light-tinged brown. Add chopped leaves one by one; first add drugs which have thick leaves followed by thin. Then mix thoroughly and fry together till coconut scrapings attain a brown colored should be divided into two equal parts and made into 2 pottalis (Average weight of a standard pottali is 300-350 gm).

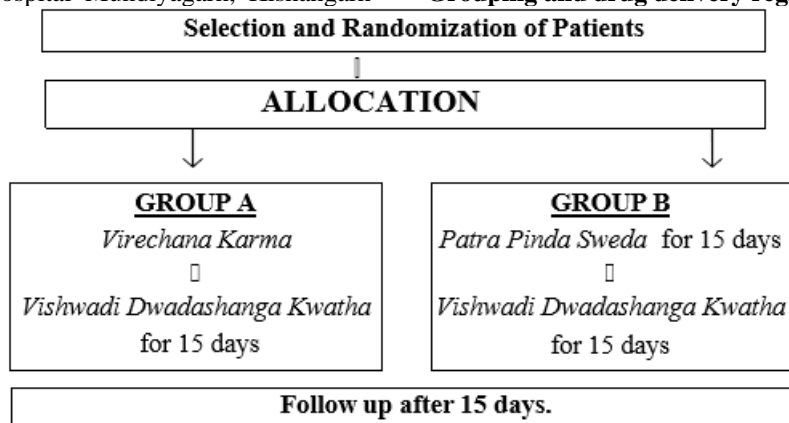
**Treatment period** – 15 days

**Method of administration of *Viswadi Dwadashanga Kwatha***- Oral route

**Dosage for *Viswadi Dwadashanga Kwatha*** – 20 gm B.D. (Morning and Evening) BeforeMeal.

**Assessment:** Based on primary and secondary parameter assessment will be done on 0day, 15-day, 30-day, 45 day.

### Grouping and drug delivery regimen



**Procedure:**

Sr. No	PROCEDURE	DRUG AND DOSE	DURATION
1.	<i>Deepana -PachanaSnehan</i> <i>Snehan-Swedana</i> <i>Virechana Karma</i> (As per SOP of <i>Panchkarma</i> ) <i>Sansarjan Karm</i>	<i>Gandhak Vati</i> 2tab bd <i>Cow Ghee</i> <i>Dasmool tail &amp; Dasmool Kwath</i> <i>Trivrit Leha Yoga</i> with luke warmwater	5 days 3 to 7 days 4 days 3-7 days 15-23 days
2.	<i>Patra Pinda Sweda</i> (As per SOP of <i>Panchakarma</i> )	for local application used	15 days
3	<i>Vishwadi DwadashangaKwatha</i>	20 GM BD (Morning and evening before meal) with luke warm water	15 DAYS

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