# Chapter 5
# Methodology

## 5.0 Methodology

**5.1 Subjects**: Eighty-six individuals who were clinically diagnosed with migraine headache were screened based on inclusion and exclusion criteria and sixty subjects were selected for the study. The recruitment was based on self-selection by the subjects to either Ayurveda or Yoga (AY) or Control (CT) groups. Subjects were explained about the study protocol and a signed informed consent was obtained before recruitment. They were also given the choice to withdraw from the study at any stage.

**5.1.1 Inclusion criteria**:

- Subjects belonging to both genders
- Between 18-46 years of age
- With a headache history of more than one year
- 5 or more attacks of headache in the last 3 months
- Willingness to take oral Ayurveda medicine, practice Yoga and follow the dietary restrictions for 75 days
- Willingness to complete the headache dairy

The diagnostic criteria were based on the International Classification of Headache Disorders (3rd edition) of the International Headache Society (International Headache society, 2013).

**5.1.2 Exclusion criteria**:

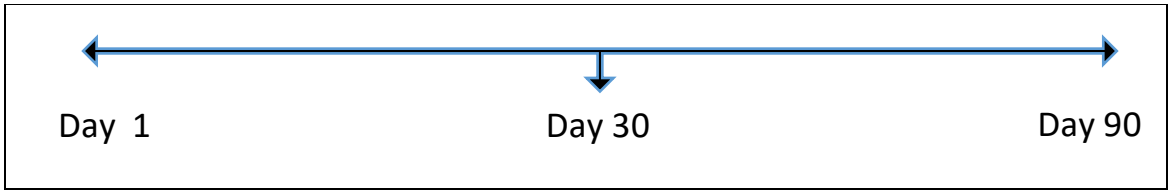
- Neurological conditions such as tumors, neurocysticercosis and stroke.
- Subjects with primary psychiatric disorders (depression, anxiety, psychosis)
- Major medical illness like renal, hepatic, neurological and cardiac diseases
- Pregnancy, pure menstrual migraine
- Subjects on Ayurveda or Yoga intervention for the past six months
- Subjects on conventional prophylactic treatment

**5.1.3 Sample size**: The sample size was calculated using the G Power software from a previous study (John et al., 2007) with an effect size of 1.31, $\alpha = 0.05$ and power = 0.95. The required sample size was 19 subjects in each group. Considering the compliance-related issues, and to improvise the statistical impact, a sample size of 30 subjects in each group was considered.

**5.1.4 Ethical considerations**: The subjects were recruited from a Holistic Health Center, Bengaluru, Karnataka in South India. The study protocol was approved by the Institutional Ethics Committee (RES/IEC-SVYASA/23/2013) and it was conducted between 2015-2017. The study was registered with the Clinical Trials Registry of India (CTRI/2017/10/010074).

## 5.2 Design of the study

The present study was a prospective, open-labelled, matched controlled trial. Subjects were recruited as and when they approached the physician who referred them to the investigator. Subjects willing to undergo Ayurveda and Yoga intervention were allocated to AY group, while the others who chose to continue with symptomatic treatment were recruited to the Control (CT) group. The groups were matched for age and gender. Subjects of AY group and CT group were assessed on Day 1, Day 30 and 90. The assessments were carried out in headache-free states and in non-menstrual phase in case of female subjects.



# Consort Table

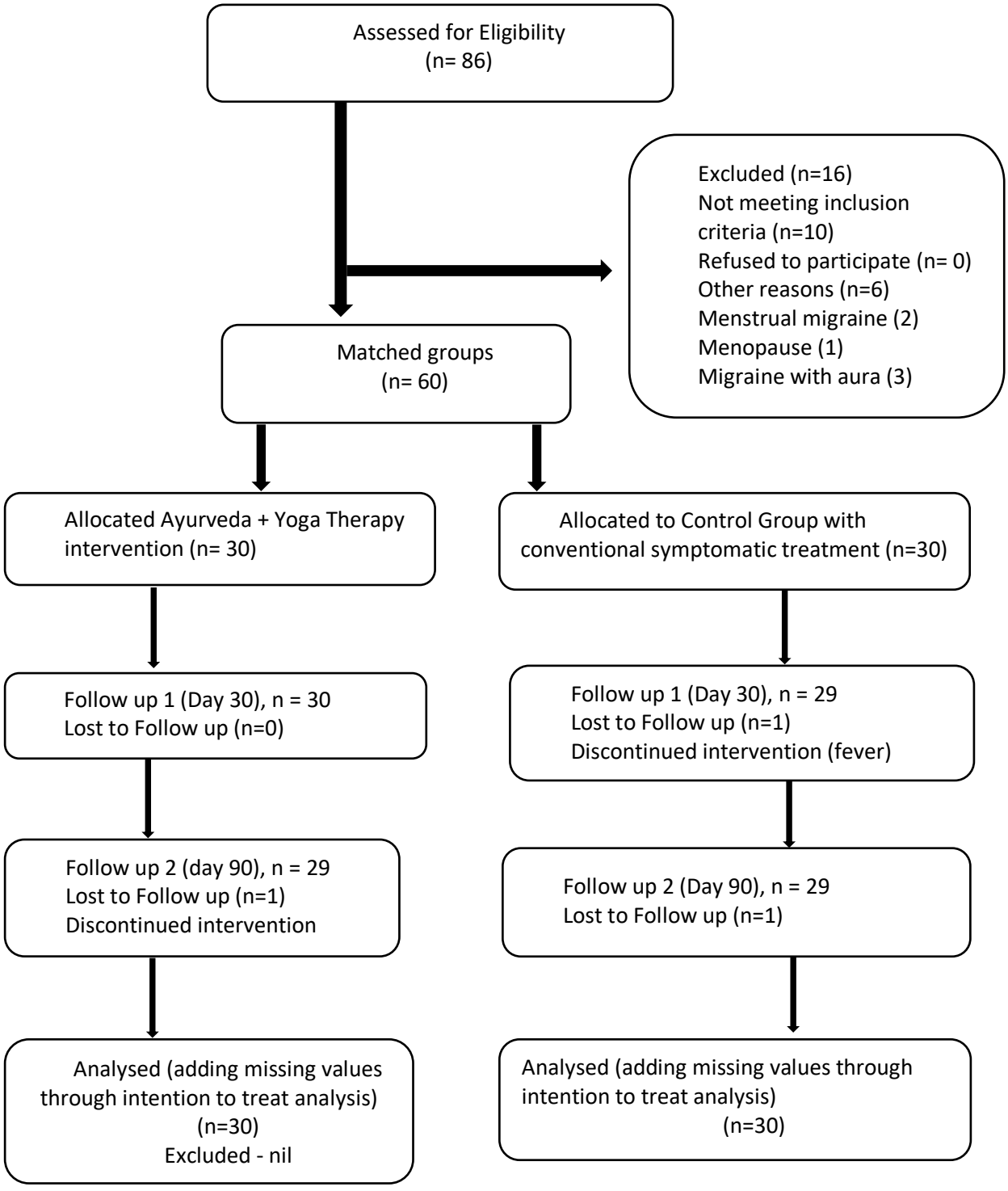



**Fig 15**: Details of the subjects from the inception till the completion of the study

### 5.3 Assessments

After the subjects volunteered for the study, the *Suśruta Prakṛti* Inventory was administered to subjects belonging to both groups as one-time assessment to understand their body constitution. Comprehensive Headache related Quality of life Questionnaire (CHQQ) and Visual analogue scale (VAS) were administered to both the groups on day 1 and day 90 of the study. The migraine disability assessment (MIDAS) questionnaire, symptom checklist, perceived stress scale (PSS-10) questionnaire was administered and the autonomic function and electromyogram recording was carried out on day 1, day 30 and day 90. The assessments were carried out in headache free states.

**Assessments on Day 1 and Day 90**

- *Suśruta Prakṛti* Inventory- Day 1only
- Comprehensive Headache related Quality of life Questionnaire (CHQQ)
- Visual analogue scale (VAS)

**Assessments Day 1, Day 30 and Day 90**

- Migraine disability assessment (MIDAS)
- Symptom checklist
- Perceived stress scale (PSS-10)
- Autonomic measures and Electromyogram

**5.3.1 *Prakṛti* Analysis**: The Body constitution (*Prakṛti*) was assessed using *Suśruta Prakṛti Inventory* (SPI) which has two parts i.e., SPI-Q (Questions) with 90 items and SPI-C (Check list) with 60 items. Subjects were asked to answer all 90 questions of SPI-Q, while an Ayurveda physician evaluated the SPI-C. The scoring of SPI-Q and SPI-C were added to quantify the proportion of the

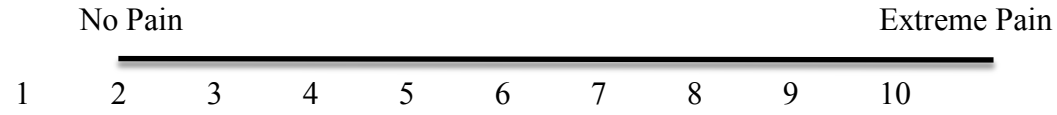
*Tridoṣa* (three body humors) of respective subjects. *Suśruta Prakṛti* Inventory (SPI) is a standardized tool for assessing Body constitution *(Prakṛti)* and combination of *doṣa* of an individual. SPI has been assessed for reliability and validity in the Indian population with a test-retest reliability for *Vāta, Pitta and Kapha* items as 0.994, 0.975 and 0.976 respectively based on Pearson Correlation coefficient. The Content and consensual validity based on Cronbach's alpha was between 0.61 and 0.80 respectively (Ramakrishna et al., 2014).

**5.3.2 Symptom Checklist**: It was used to understand the influence of Ayurveda and Yoga on number and severity of symptoms. The symptom check list had 10 questions based on the number of attacks, duration of an attack, intensity of pain, use of analgesics, associated with nausea and or vomiting. The checklist was completed based on an individual's experience of the above mentioned symptoms over the past three months. The intensity of being moderate or severe was assessed based on the pointer which was set between 1-10, where 1-3 was considered as mild, 4-6 was considered as moderate and 7-10 was considered severe.

**5.3.3 Comprehensive headache related quality of life (CHQQ)**: CHQQ is a 23 item questionnaire, used to understand the subjective experience of Quality of Life of an individual and to note the way in which migraine headache affected their daily life. The questionnaire has been found to be reliable with Cronbach's alpha being 0.913 for the whole instrument when used in Migraine and Tension Type Headache patients. The questions have been categorized under physical, mental and social dimensions with a total score of 0-100 (Manhalter et al., 2012).

**5.3.4 Visual Analogue Scale (VAS)**: The scale included a 10 cm long straight line, marked with 'No Pain' on one side and 'extreme pain' on the other side. The VAS was used to assess

the head- ache intensity on Day 1and Day 90. Subjects were asked to mark the pain level on the straight line by drawing a perpendicular line. A measuring scale was used to identify the self rated pain intensity between 0 and 10 (Haefeli & Elfering, 2006).




The Visual Analogue Scale

### 5.3.5 Migraine Disability Assessment (MIDAS):

MIDAS is a short self-administered questionnaire used to quantify headache-related disability in a span of 3 months (Stewart et al., 1999). It has a set of five questions and the total score is based on the number of days marked against each question. The grades and respective scores are mentioned in **Table 1.**

| Grade | Disability | Score |
|---|---|---|
| I | Little or No Disability | 0-5 |
| II | Mild | 6-10 |
| III | Moderate | 11-20 |
| IV | Severe | 21+ |

**Table 1:** The 4-point grading system for Migraine Disability Assessment Questionnaire

### 5.3.6 Perceived Stress Scale 10 (PSS):

PSS measures the perceived level of stress as a function of objective stressful events, coping processes and personality factors. PSS-10 was selected due to its superior psychometric properties (Cohen & Williamson, 1988). Each item is rated on a 5-point scale ranging from never (0) to almost always (4).

### 5.3.7 Autonomic Variables and Surface Electromyography (sEMG):

An 8 channel fully integrated data acquisition system (Power lab 15T) from AD instruments, Australia was used for simultaneous recording of Respiration, Electrocardiography (ECG) and Surface Electromyography (sEMG).

Assessments were done in a dimly lit, sound attenuated room.

Subjects were asked to sit on an armless chair with back support by placing their feet on a non-conducting material.

During recordings, they were instructed to close their eyes and maintain normal breathing. Respiration, ECG and sEMG were recorded simultaneously for a duration of 3 minutes during frowning (by raising the eyebrows) which produced voluntary muscle contraction.

*5.3.7a The Electrocardiogram (ECG)* was recorded using standard limb lead II configuration by placing clamp ECG electrodes with electrode gel. Data were acquired at a sampling rate of 1024 Hz. The heart rate variability was derived from ECG by computing the successive RR intervals.

*5.3.7b Respiratory rate* was recorded through a piezo respiratory belt transducer. This was used to generate a voltage with a change in thoracic circumference due to respiration. The output range was between 20 mV to 400 mV with a sensitivity of 4.5± 1mV/mm.

*5.3.7c The sEMG of the Frontalis muscle* was recorded using two pre-gelled silver chloride electrodes placed on the forehead with a distance of 2 cm between them and approximately 2.5 cm above each eyebrow along with a shared ground electrode (Gada MT., 1984). The sEMG was recorded with a sampling rate of 1000 Hz, the bandwidth of 20–500 Hz and a maximum input impedance of 5 ohms. low pass notch filter was applied at 50Hz.

**5.4 Intervention**:

Ayurveda treatment of *Virecana* (therapeutic purgation) followed by Yoga therapy was given to the subjects of AY group while the Control (CT) group were allowed to continue with conventional symptomatic treatment which was prescribed by the consulting physician.

**5.4.1 Ayurveda and Yoga Therapy:**

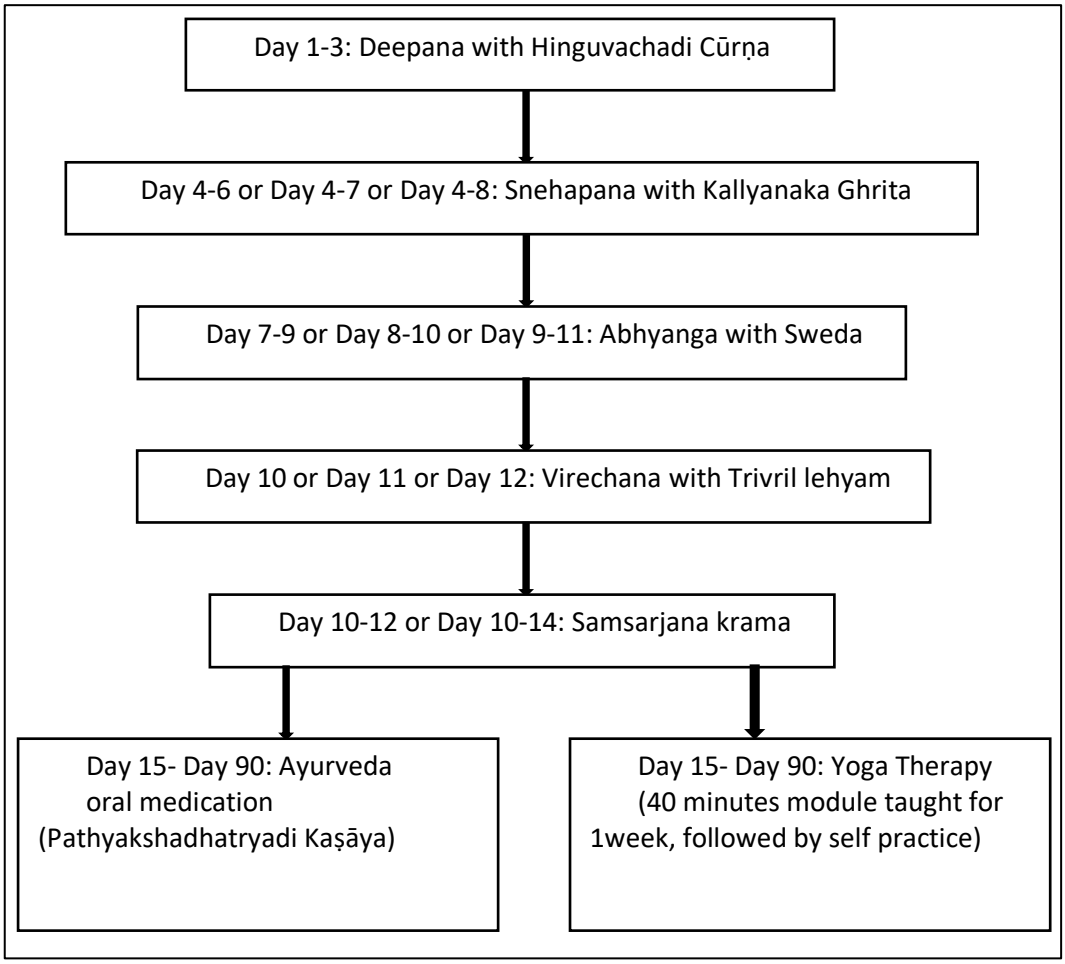



**Fig 16**: Ayurveda Intervention

*5.4.1a* **Ayurveda intervention**

Following the assessments on Day 1

- *Deepana - Pachana* (Stomachic and Digestive) 2.5 grams-5 grams of *Hinguvachadi cūrṇa* (poly herbal powder) was given twice a day after food in the morning and evening with warm water for first 3 days.
- From Day 4, subjects were advised to apply warm oil by gentle rubbing across the body at home in the morning anytime between 6am to 7am. Bath with hot water was advised following oil application. Subjects were cautioned about keeping themselves warm maintain regulated diet and lifestyle. A hand out was provided to them about Do's and Don'ts during *Snehapāna*. (**Table: 2)**

**Treatment protocol:**

- The subjects were asked to report to the Holistic health center for *Abhyantara snehapāna* (internal oleation) between 7am to 8am on empty stomach. The internal oleation with *Kalyāṇaka ghṛta* (poly herbal preparation made with clarified butter) (Yadunandan, 1997) was administered on empty stomach in *arohana pramana* (increasing dosage) for 3-5 days (upto day 6/day 7/day8 counted from from first day of *deepana -pachana*) until *Samyak Snighdha Lakshanas* (adequacy of internal oleation) were seen (28). The minimum dosage of the *ghṛta* (clarified butter) was 30 ml and the maximum dosage was 150 ml. The subjects were followed up over phone every 3 hours to understand the progress and also monitor them.
- The following morning the subjects were evaluated to check the *snigdhata* and the dosage of the day was decided. The subject had to repeat the process of oil application and follow the process till *samyak snigdha lakshanas* were seen.
- After a minimum number of 3 days or maximum number of 5 days of *snehapāna, sarvanga Abhyaṅga* (external oil application) with *Śuddha Tila taila* (Pure Sesame oil)

and *swedana* (steam bath) was administered at the center for 3 days. This was between day 7/day 8/day 9 to day 9/day10/day 11 based on the completion of *snehapāna* for 3, 4 or 5 days. A trained Ayurveda female or male therapist attended to the female and male subjects respectively. The *Abhyaṅga* was carried out for 45 minutes and the *swedana* for 10-12 minutes based on the sign of sweating. The therapist was instructed to stop the *swedana* given through a sitting wooden steam unit when he/she noticed sweating on the forehead.

- Following 3 days of *Abhyaṅga* and *swedana*, either on day 10 or day 11 or day 12, *Virecana* (Therapeutic Purgation) was induced by administering *Trivrit lehyam* (poly herbal paste) (Yadunandan, 1997) based on their *Prakṛti* (body constitution) and *Koshta* (nature of the digestive tract). The minimum dosage administered was 50 grams and the maximum was 75 grams. It was advised to be taken on empty stomach anytime between 6am to 7am at the home of the subject. All instructions were previously given and a hand out provided for reference. On hourly basis the subjects were followed up and the number of episodes were being checked. Subjects were also being questioned on aspects of discomfort. Subjects were advised to take 2-3glasses of starch water following a warm water shower after completion of *Virecana*.
- As documented in an earlier study, the process of *Virecana* was safe and efficacious with no imbalance in serum electrolyte levels (Rais A & Bhatted S, 2013). *Samsarjana krama* (dietary regimen) for minimum of 3 days (Day 10 or 11 or 12 to Day 12 or 13 or 15 respectively) was specified based on the *śuddhi* (degrees of cleansing) (Acharya, 2006). If the *virecana* indicated *madhyama śuddhi*, 5 days of *samsarjana* was indicated.

  *Śuddhi* is defined as the effect resulted in the patient due to the expulsion of *doṣā* (morbid factors) by administration of *Pañcakarma* procedures. The following two parameters are primarily considered to assess the type of *śuddhi*.

*Śuddhi* attained by *Virecana* is graded into three types depending on the number of purgative bouts after the omission of first two bouts initially. Bouts ranging from 1-10, 11-20 and 20-30 are graded as *avara* (least), *madhyama* (medium), and pravara (excellent) type of *Śuddhi* requiring 3 days, 5 days and 7days of *samsarjana*. Most of our subjects were given the required dosage of purgative targeting *Madhyama śuddhi.*

- The subjects were asked to come for a follow up the next morning following *Virecana.* The dietary advice was provided and the *shamana auṣadhi* (oral pacificatory medicines) were suggested.
- *Shamana auṣadhi* (oral pacificatory medicines) were started from day 15- day 17 (depending on 3or 5 days of *samsarjana karma*) and continued for a span of 75 days. It was started on Day 15 for all subjects to maintain the structured intervention. The subjects were advised to take the oral medicine upto day 90. The following were used:
- *Pathyakṣadhātryādi Kaṣāya* (poly herbal decoction) (Shastri, 1985): 15 ml, 30 minutes before breakfast and dinner with 45 ml of warm water.
- *Kacorādi cūrṇa* (poly herbal powder) (Niteshwar & Vidayanath, 2007): Topical use as a paste mixed with milk (at room temperature) on the forehead once a day. (The composition of each polyherbal formulation and the dosage are mentioned in **Table - 3**)
- There was special mention of *pathya* and *apathya* (Do's and Don'ts regarding diet and lifestyle). The subjects were asked to maintain vegetarian food habit, eating out in restaurants, avoid triggers of stress and sleep maximum by 11.00 pm
- The subjects were allowed to take oral analgesics (Non steroidal anti inflammatory drugs-NSAID), as and when required based on the intensity of pain tolerable to them and the same was noted in their dairy for medication use.
- All the subjects were followed up on Day 15 or Day 17 and Yoga therapy module was started on the same day (15 or 17).

- The follow ups were taken up once in a week over a phone call to assess the regularity of medicine, Yoga therapy and also to keep the subjects motivated.
- All subjects were asked to maintain a headache diary (Details in **Table 4**) and were advised to meet the investigator at any given point of time in case they had any query.

**Table 2**: Handout with description on diet and lifestyle modification during Virecana

**PROCEDURES TO BE FOLLOWED DURING VIRECHANA (PURGATION)**

During **Snehapana**

1. Drink hot water (30ml) once in every 20- 30min.

2. Observe the taste of the medicine after every burp.

3. Wait until the burp is clear.

4. After a clear burp, eat only freshly prepared rice and dal (It could vary from 6-8 -12 hours from medication)

5. After food, drink warm water once in 1 to 2 hours.

6. Through out the treatment drink only warm water.
**Note**: Do not deviate from the instructions written above

Please call us for any doubts

**Other precautions:**

Do not expose to breeze.a/c or external environment.

Do not sleep during the day.

Avoid work pressure. Take off from work

**Food items to be used ->** Toor dal, Moong dal yellow, ghee, cumin seeds, Turmeric, salt, curry leaves, coriander, little salt, Regular rice

**During steam bath**

**Food recommended**
Breakfast: kichadi/pongal

Lunch: Rice+ rasam or phulka (thin roti) +vegetables (beans, carrot, bottle gourd )

Dinner: Rice+ rasam/dal (thinly cooked)
Ingredients:-For rasam- as above with jaggery, ginger, red chilly powder, black pepper powder, tamarind, carrot, beans, bottle gourd

| | Morning | Afternoon | Night |
|---|---|---|---|
| Day 1 | | starch water (Manda) | starch water |
| Day 2 | Starch water/Rice along with water (Peya) | Rice with water (Peya) | Rice with water (Peya)/ Khichadi |
| Day 3 | Rice with water/ Soft rice with Mung dal soup (green gram soup) | Soft rice with Mung dal soup (green gram soup) | Soft rice with Mung dal soup (green gram soup) |
| Day 4-Review with Doctor | Start with Khichadi (For 3 days of dietary advise) | | |
| Day 4 | Soft rice with Mung dal soup (green gram soup) | Khichadi+Ghee | Khichadi+Ghee |
| Day 5 | Khichadi | Rice + rasam+ Boiled vegies | Rice + rasam+ boiled vegies |

**Table 3- Composition of Polyherbal combinations**

**3a:** ***Hiṅguvacādi cūrṇa*** (Yadunandan, 1997) (*Aṣṭāṅga Hrudaya. Cikitsā sthana*. Chap 14/ 31-33):

It is prepared with one part of each of the ingredients mentioned below. They are powdered separately and mixed together.

Dosage: 2.5grams - 5 grams, 30 minutes before food with warm water.

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**Table 3a**: Composition of *Hiṅguvacādi cūrṇa*

| **Sanskrit name** | **Botanical name** |
|---|---|
| *Śuddha Hingu* | Ferula asafetida |
| *Vacha* | Acorus calamus |
| *Vijaya* | Terminalia chebula |
| *Pashugandha* | Cleome gynandra |
| *Dadima* | Punica granatum |
| *Dipyaja(Ajwain)* | Trachyspermum ammi |
| *Dhanya* | Coriandrum sativum |
| *Pata* | Cyclea peltata |
| *Pushkaramoola* | Inula racemose |
| *Shati* | Hedychium spicatum |
| *Hapusha* | Sphaeranthus indicus |
| *Agni* | Plumbago zeylanica |
| *Yavakshar* | Alkali preparation made of Hordeu vulgare |
| *Svarjika kshara* | Sarjika kshara |
| *Saindava lavana* | Rock salt |

| | |
|---|---|
| *Sauvarchala lavana* | Black salt |
| *Vida lavana* | Type of black salt |
| *Shunti* | Zingiber officinalis |
| *Maricha* | Piper nigrum |
| *Pippali* | Piper longum |
| *Ajaji* | Cuminum cyminum |
| *Chavya* | Piper chaba |
| *Tintidika* | Rhus parviflora |
| *Vetasamla(Amlavetasa)* | Garcinia morella |

**3b-** ***Kalyāṇaka ghṛta*** (Yadunandan U., 1997) (*Aṣṭāṅga Hṛdaya, Uttarasthana*. Chap 6/ 26-28): 12g each of the below mentioned ingredients are used to make a medicated ghee (clarified butter).

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**Table 3b**: Composition of *Kalyāṇaka ghṛta*

| **Sanskrit name** | **Botanical name** |
|---|---|
| *Haritaki* | Terminalia chebula |
| *Vibhitaki* | Terminalia bellirica |
| *Amalaki* | Emblica officinalis |
| *Vishala* | Citrulus cholocynthis |
| *Bhadra ela* | Amomum subulatum |
| *Devadaru* | Cedrus deodara |
| *Elavaluka* | Prunus avium |
| *Sariva* | Hemidesmus indicus |
| *Haridra* | Turmeric |

| | |
|---|---|
| *Daruharidra* | Berberis aristata |
| Shalaparni | Desmodium gangeticum |
| Prishnaparni | Uraria picta |
| Phalini | Callicarpa macrophylla |
| Nata | Valeriana wallichi |
| Brihati | Solanum indicum |
| Kushta | Saussurea lappa |
| Manjishta | Rubia cordifolia |
| Nagakeshara | Mesua ferrea |
| Dadimaphalatwak | Punica granatum |
| Vella | Embelia ribes |
| Talisapatra | Abbies webbiana |
| Ela | Elettaria cardamomum |
| Malati | Jasminum sambac |
| Utpala | Nymphea stellate |
| Danti | Baliospermum montanum |
| Padmaka | Prunus poddum |
| Hima | Sandalwood -Santalum albu |
| Sarpi | ghee – 768 g |

**3c- *Trivrit Lehyam*** (Yadunandan U., 1997) (*Aṣṭāṅga Hṛdaya. Kalpasiddhi Sthana*. Chap 2/9).

*Trivrit* – Operculina turpethum

Preparation: 25 grams of the powder is added with 400 ml of water, boiled and reduced to 100 ml, filtered. To this *Trivrit Kaṣāya*, 25 grams of *Trivrit* powder is again added, along with 50 grams of sugar and mixed well. 25 ml of honey and 5 grams of each of cinnamon, cardamom and cinnamon leaves fine powder is added to obtain the sweet paste.

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**Table 3c**: Composition of *Trivrit Lehyam*

| Sl. No. | Ingredients | Quantity |
|---|---|---|
| 1 | *Trivrit Kaṣāya* | 100 ml |
| 2 | *Trivrit Cūrṇa* | 25 grams |
| 3 | Sugar | 50 grams |
| 4 | Honey | 25 ml |
| 5 | Cinnamon | 5 grams |
| 6 | Cardamom | 5 grams |
| 7 | Cinnamon leaves powder | 5 grams |

**3d-*Pathyakṣadhātryādi Kaṣāya*** (Shastri P., 1985)

Herbal decoction is prepared from 10 grams each of the following herbs

Dosage-15 ml twice daily before breakfast and dinner mixed with 45 ml of warm water.

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**Table 3d**: Composition of *Pathyakṣadhātryādi Kaṣāya*

| Sanskrit name | Botanical name |
|---|---|
| *Pathya* | Terminalia chebula |
| *Aksha* | Terminalia bellirica |
| *Dhatri (Amla)* | Emblica officinalis |
| *Bhunimba* | Andrographis paniculata |
| *Nisha (Turmeric)* | Curcuma longa |
| *Nimba (*Neem) | Azadirachta indica |
| *Amruta* | Tinospora cordifolia |

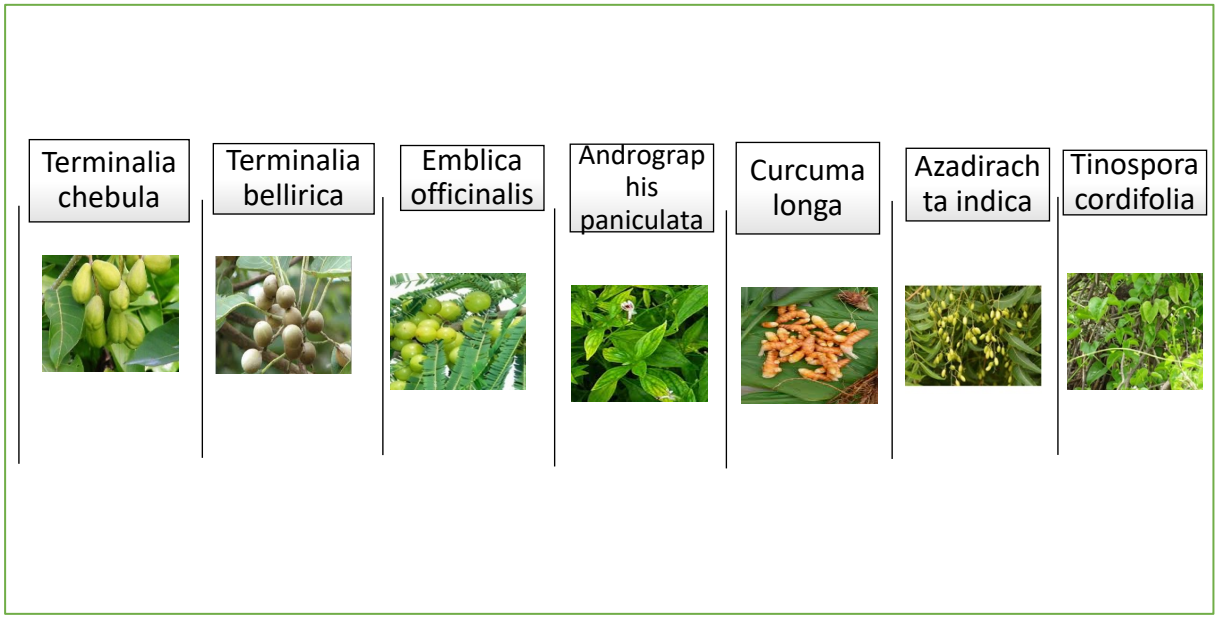


**Fig 17:** The seven herbs in *Pathyakṣadhātryādi Kaṣāya*

**3e- *Kacorādi cūrṇa*** (Niteshwar K, Vidayanath R., 2007).

Equal quantities of herbal powders mentioned below are used to make the powder.

Dosage- ½ tsp to be mixed with milk and applied on the forehead.

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**Table 3e**: Composition of *Kachoradi Cūrṇa*

| ***Sanskrit name*** | **Botanical name** |
|---|---|
| *Kachora* | Curcuma zedoaria |
| *Dhatri* | Emblica officinalis |
| *Manjishta* | Rubia cordifolia |
| *Yashti* | Glycyrrhiza glabra |
| *Daru* | Cedrus deodara |
| *Silajitu* | Asphaltum |
| *Vedhi* | Ferula foetida |
| *Rohini* | Andrographis paniculata |
| *Tintrinisira* | Tamarindus indicus |
| *Kumkuma* | Crocus sativus |
| *Indu* | Camphor |
| *Varivaha* | Cyperus rotundus |
| *Rochanam* | Mallotus phillippenensis |
| *Bala* | Sida cordifolia |
| *Laja* | Oryza sativa |
| *Jala* | Coleus zeylanicus |
| *Usira* | Vetiveria zizanioides |
| *Pushkaramoola* | Innula racemosa |

**Table 4: Headache Diary**

| Day | Date | Any episode of headache (Y/N) | If Yes- Duration | Nausea/ Vomiting | Relieved with analgesic/ pain killer tablet (Y/N) | If Yes- No. of tablets | Time of Yoga | Ayurveda medicine (+/-) | Sleep time |
|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | | |
| 2 | | | | | | | | | |
| 3 | | | | | | | | | |
| 4 | | | | | | | | | |
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| 10 | | | | | | | | | |
| 11 | | | | | | | | | |
| 12 | | | | | | | | | |
| 13 | | | | | | | | | |
| 14 | | | | | | | | | |
| 15 | | | | | | | | | |

*5.4.1b* **Yoga therapy**

The specially designed integrated Yoga therapy module for migraine included *Śithilīkaraṇa vyayama* (loosening exercises), *śvāsa kriya* (breathing exercises), *āsanas* (postures), *prāṇayama* (regulated breathing), relaxation techniques and chanting. Yoga was practiced for 40 minutes daily beginning from Day 15 or 17 of the treatment for 7 days as personalized sessions under the supervision of a trained Doctor. The subjects were asked to practice the same module at home, 5 days a week until day 90. Female subjects were advised not to practice yoga during the first three days of menstrual cycle. All subjects were monitored over phone The Yoga therapy module is detailed in **Table 5**.

**Table 5:** Details of Yoga program specially designed for the Migraine patients are listed below. The description includes the category of practices, duration of each practice, number of repetitions, and the sequence of practices.

| **Sl.No** | **Practices** | **Number of rounds** | **Duration** |
|---|---|---|---|
| | **Loosening practices (*Śithilīkaraṇa vyayama*)** | **5 rounds** | **5 minutes** |
| | Neck up and down movement<br>Neck side to side movement<br>Shoulder rotation- Clockwise and Anti clockwise<br>Shoulder cuff rotation -Clockwise and Anti clockwise<br>Head rolling - Clockwise and Anti clockwise, Up and Down movement | | |
| | **Instant Relaxation Technique** | **1 Round** | **1 minute** |
| | **Breathing Practices (*śvāsa kriya*)** | **5 rounds each** | **5 minutes** |
| | Ankle stretch breathing<br>*Shashankāsana* breathing | | |

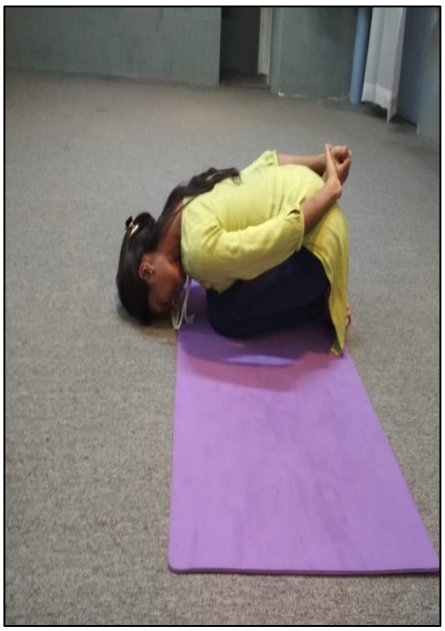
| | | | |
|---|---|---|---|
| | Tiger stretch breathing<br>*Uttanapādāsana* breathing- Single leg | | |
| | **Quick Relaxation Technique** | **1 round** | **3 minutes** |
| | **Postures (*Āsanas*)** | **1 round each** | **12 minutes** |
| 5a | Standing:<br>*Pādahasthāsana*<br>*Ardha Chakrāsana*<br>*Ardhakati Chakrāsana*<br>*Trikonāsana* | 30 seconds each approximately | 2.5 minutes |
| | Relaxation in standing posture | 30 seconds | 30 seconds |
| 5b | Sitting:<br>*Janushirāsana*<br>*Vajrāsana*<br>*Ushtrāsana*<br>*Shashankāsana*<br>*Suptavajrāsana*<br>*Vakrāsana* | 30 seconds each approximately | 4 minutes |
| | Relaxation in sitting posture | 30 seconds | 30 seconds |
| 5c | Supine:<br>*Viparita karani/ Sarvangāsana*<br>*Matsyāsana*<br>*Pavanamukthāsana*<br>*Naukāsana*<br>*Setubandhāsana* | 30 seconds each | 2.5 minutes |
| | Relaxation in supine position | 30 seconds | 30 seconds |

| | | | |
|---|---|---|---|
| 5d | Prone:<br>*Bhujangāsana*<br>*Shalabhāsana*<br>*Dhanurāsana* | 30 seconds each | 1.5 minutes |
| **6.** | **Deep relaxation technique** | | **7 minutes** |
| **7.** | **Cleansing(*Kriyas*)**<br>*Kapālabhati* | | **1 minute** |
| **8.** | **Regulated breathing practices (*Prāṇayama*)** | **1 minute each** | **3 minutes** |
| | *Nadiśodhana Prāṇayama*<br>*Bhramari Prāṇayama*<br>*Ujjayi Prāṇayama* | 1 minute each | 3 minutes |
| **9.** | ***Nādānusandhāna* ( chanting )** | | **3 minutes** |

**Yoga Therapy practices**: (Includes Loosening exercises, Breathing Practices, *Āsana*, Relaxation, *Prāṇayama, Nādānusandhāna*).

Neck loosening

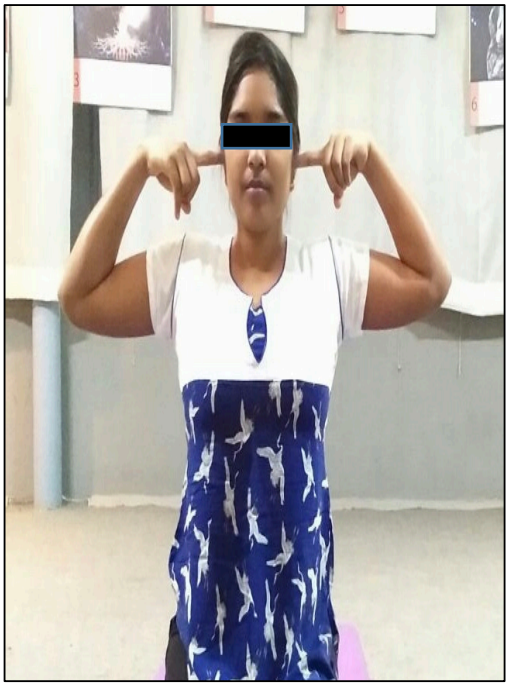
Head Rolling



śaśāṁkāsana Breathing


Trikoṇāsana

Shavāsana



Bhrāmari

Nādānusandhāna

### 5.4.2 Control Group:

The subjects who agreed to participate in the trial but preferred to continue on oral analgesics (Non-Steroidal Anti Inflammatory Drug's) for symptomatic relief as per the prescription of a general physician or neurologist were included under this group.They were asked not to practice Yoga nor follow Ayurveda during the study period.They were given an option to undergo the same therapy protocol as given for AY group after the study period.

Subjects of both groups were monitored once in two weeks over a telephonic call and visited the investigator once a month. The subjects were free to withdraw from the study at any stage if they felt the conditions weren't conducive.

## 5.5 Data Extraction and Analysis

### 5.5.1 Data extraction

*5.5.1a* **Questionnaires**

- *Suśruta Prakṛti Inventory* (SPI) questionnaire: Each item marked in the two parts i.e., SPI-Q (Questions) with 90 items and SPI-C (Check list) are given a score of '1'. Each of them are scored separately and the total from SPI-Q and SPI-C is considered for analysis

- Symptom Checklist: The Yes/No marked against all 10 symptoms was noted. The average duration of headache in hours and the number of analgesic tablets used for noted in numerical values. Number of subjects with severe headache, with nausea and/ or vomiting and number of subjects with analgesic requirement on need were also noted in a spread sheet.

- Comprehensive headache related quality of life (CHQQ): The scores marked between 0-5 (5 point Likert scale) for each item were noted in the CHQQ calculator spread sheet

which was provided by the team who designed CHQQ. The values were transformed further into a score between 0-100, where 0 was ‘full restriction’ and 100 ‘absence of restriction’. The total score and the three dimensions are calculated and they are the mean values of the relevant transformed scores.

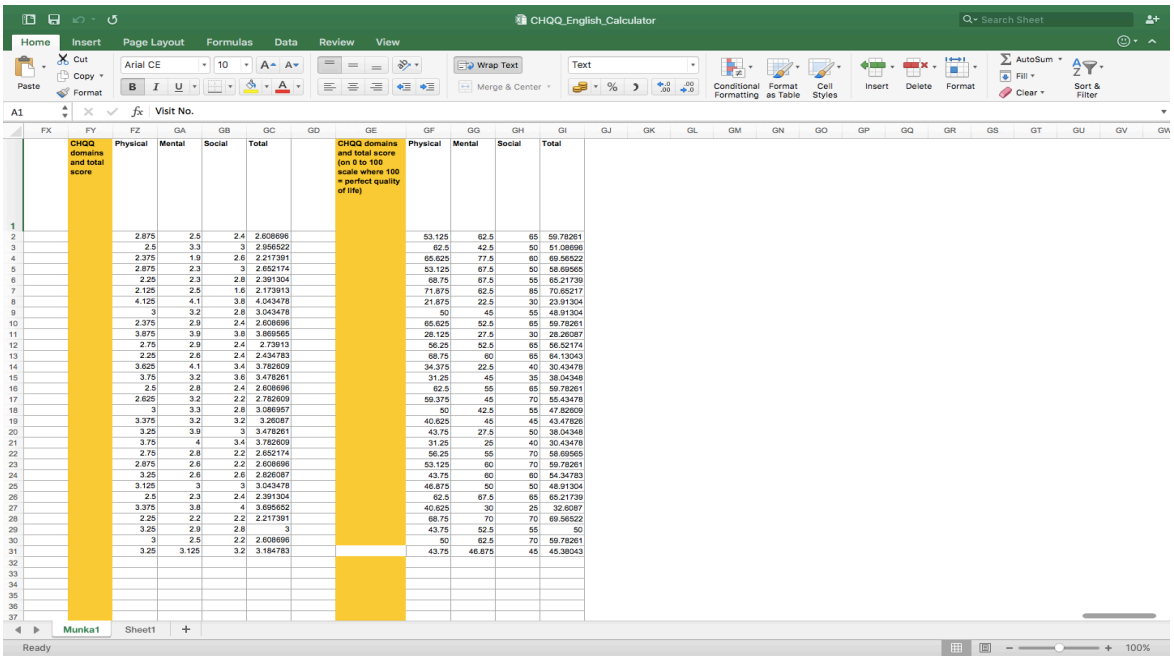



**Fig 18**: CHQQ Calculator

- Visual analogue scale: The point marked on the 10 cm line is scored and entered in the spread sheet for further analysis

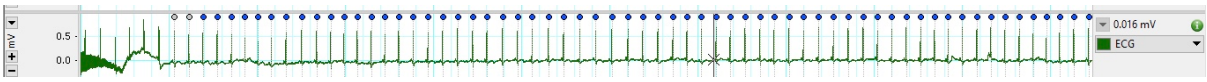
- Migraine disability assessment (MIDAS): The number marked against each question (set of five questions) by the subject is totaled. The total score available as a numerial value is tabulated based on the degree of disability as mentioned in **Table 1.**

- Perceived stress scale: The 10 item questionnaire is marked based on the 5-point scale from 0-4. Items Items 4, 5, 7, and 8 are the positively stated items and they were reverse scored. The sum of all 10 items indicated the levels of perceived stress. Scores

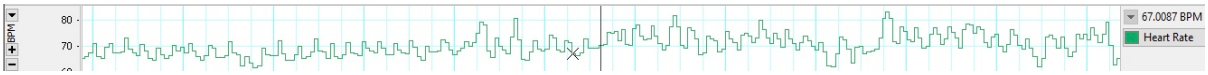
between 0-13 were considered as low stress, 14-26 as moderate stress and 27-40 as high perceived stress.

*5.5.1 b* **Autonomic Variables**: Lab Chart 8 software was used to extract the data offline. Pulse, Respiration, ECG and EMG were used to derive Pulse amplitude, Respiratory rate, Heart rate, HRV, RMS EMG and Integral EMG respectively. They were derived separately from the data collected on Day 1, Day 30 and day 90. The noise-free ECG data excluding ectopic beats were selected for further analysis. Three minutes data was selected and the values were derived through the software.

*Heart rate:* It was obtained as beats per minute averaging it across the three minutes. The Lab chart software also processed the ECG signals by identifying successive RR intervals to extract both frequency domain and time domain measures of HRV. The low frequency (LF), high frequency (HF) and LF/HF ratio expressed as normalized units were used as frequency domain measures. While, the standard deviation of RR Intervals (SDNN), the square root of the mean squared differences of successive NN intervals (RMSSD), and the proportion derived by dividing NN50 by the total number of NN intervals (pNN50) were derived as time domain measures.

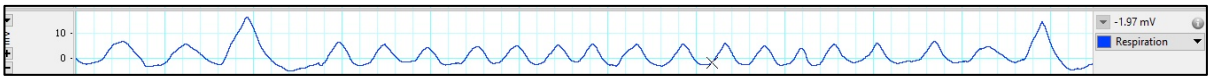



Raw ECG image recorded during frowning



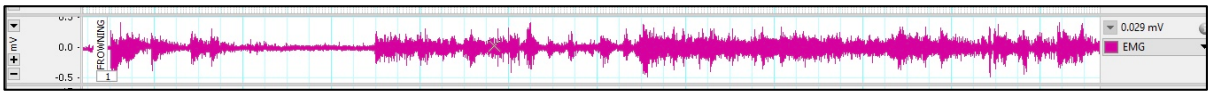

Heart Rate derived from ECG

*Respiratory rate:* It was derived as the number of breath cycles per minute after averaging it across the 3 minutes by computing successive inspiratory and expiratory cycles.

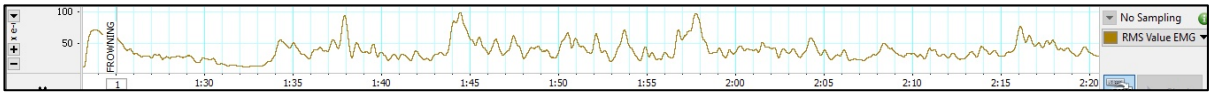



Respiratory rate recorded during frowning

*Surface Electromyogram:* sEMG recording obtained during the 3 minute voluntarily contraction was used to derive RMS EMG and Integral EMG (De Luca., 1997).



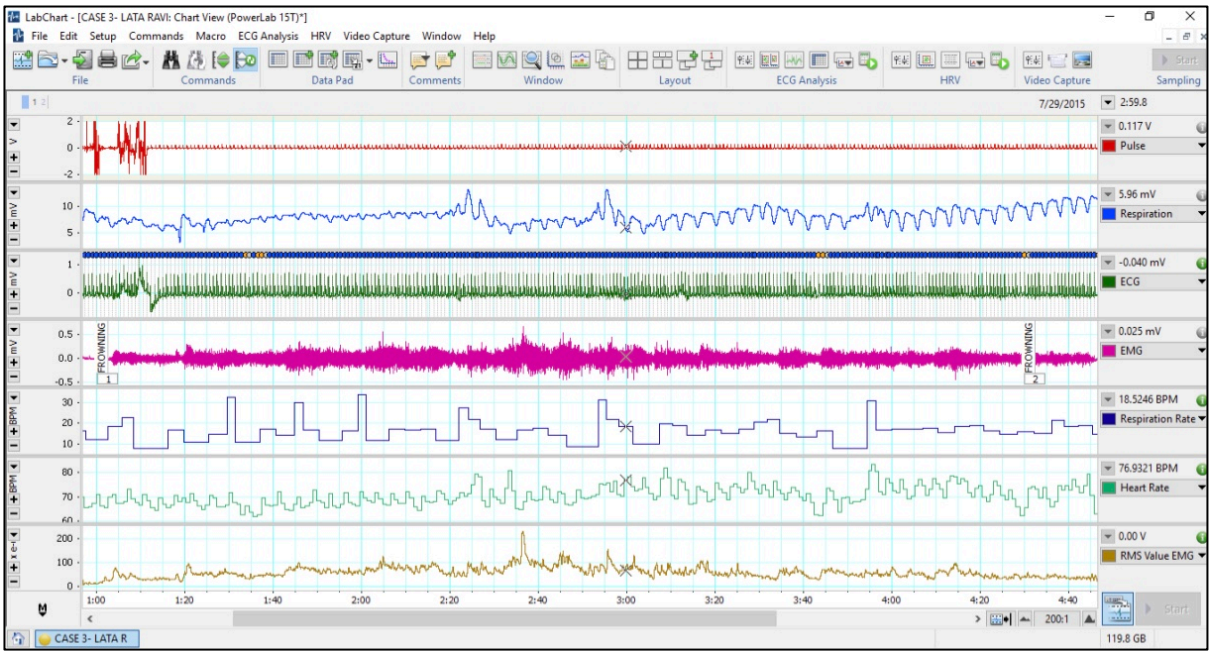

Raw sEMG image recorded during frowning



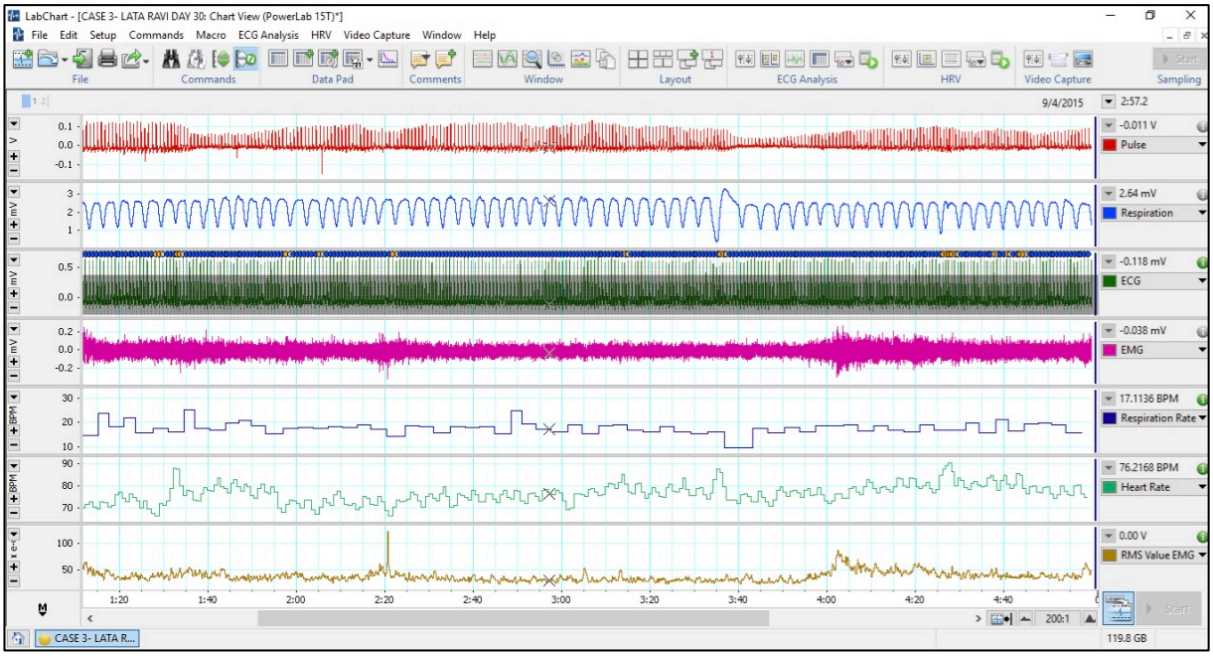

RMSEMG derived from the raw EMG


**Fig 19:** Lab Chart depicting the data extraction from the channels

Day 1



Day 30




Day 90

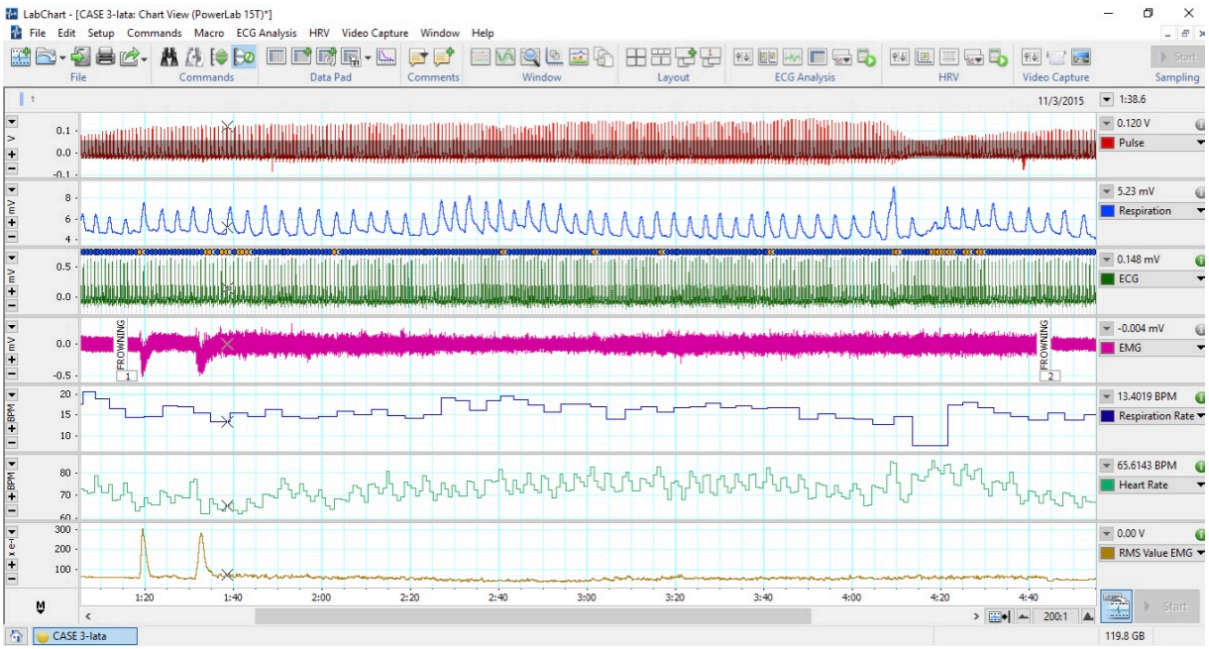



**Fig 20**: An illustrative image of the changes in autonomic variables and sEMG recorded on Day1, Day 30 and Day 90 in a subject representing AY group.

### 5.5.2 Data analysis

The data were analyzed using Statistical Packages for Social Sciences (SPSS), version 23. The normality and homogeneity were assessed using Kolmogorov-Smirnov test. The missing values were replaced by intention to treat analysis. The data of selected variables which were collected three times i.e., Day 1, Day 30 and Day 90 were analyzed using a Repeated Measures ANOVA with one Within-Subjects factor (Time) and one Between Subjects factor (Groups). Multiple comparisons were made across mean values using a post-hoc analysis with Bonferroni correction. The data of other variables collected only twice (Day 1 and Day 90) were analysed using paired't' test to understand pre-post differences within the group, while a one-way ANOVA was done to understand between group differences. The values were considered significant if $p<.05$.