OPEN CLINICAL TRIAL FOR CEGANA VATHAM USING VARMAM PROCEDURE

I. INTRODUCTION:

Most patients who present with neck pain have “non-specific (simple) neck pain,” where symptoms have a postural or mechanical basis. Aetiological factors are poorly understood[1] and are usually multifactorial, including poor posture, anxiety, depression, neck strain, and sporting or occupational activities.[2] Neck pain after whiplash injury also fits into this category, provided no bony injury or neurological deficit is present.[3] When mechanical factors are prominent, the condition is often referred to as “cervical spondylosis,” although the term is often applied to all non-specific neck pain. Mechanical and degenerative factors are more likely to be present in chronic neck pain.

In cervical spondylosis, degenerative changes start in the intervertebral discs with osteophyte formation and involvement of adjacent soft tissue structures. Many people over 30 show similar abnormalities on plain radiographs of the cervical spine, however, so the boundary between normal ageing and disease is difficult to define.[4] Even severe degenerative changes are often asymptomatic, but can lead to neck pain, stiffness, or neurological complications.

About two thirds of the population have neck pain at some time in their lives,[5] [6] and prevalence is highest in middle age. After back pain, neck pain is the most frequent musculoskeletal cause of consultation in primary care worldwide

Cervical spondylosis is usually diagnosed on clinical grounds alone, symptoms are cervical pain aggravated by movement, referred pain (occiput, between the shoulder blades, upper limbs), retro-orbital or temporal pain (from C1 to C2), cervical stiffness—reversible or irreversible, vague numbness, tingling, or weakness in upper limbs, dizziness or vertigo, poor balance, rarely, syncope, triggers migraine, “pseudo-angina”[15]. The signs are poorly localised tenderness, limited range of movements (forward flexion, backward extension, lateral flexion, and rotation to both sides), Minor neurological changes like inverted supinator jerks (unless complicated by myelopathy or radiculopathy) Although pain is predominantly in the cervical region, it can be referred to a wide area, and is characteristically exacerbated by neck movement. Neurological change should always be sought in the upper and lower limbs, but objective changes occur only when spondylosis is complicated by myelopathy or radiculopathy, or when unrelated causes like disc prolapse, thoracic outlet obstruction, brachial plexus disease, malignancy, or primary neurological disease are present.

Currently, a balanced view of the management of neck pain cannot be given by discussing evidence based treatments only. Stress management and postural advice on daily activities, work, and hobbies may be useful in some patients. Patients should be advised to use only one pillow at night. When pain is severe, analgesics and anti-inflammatory agents are widely used, despite the lack of evidence that they work. Yoga, pilates and the Alexander technique all improve neck posture, but their value in treating neck pain is uncertain.

Acute neck pain not due to whiplash injury found limited evidence of benefit for manipulation or mobilisation therapy.[3] [4] No evidence exists for the efficacy of non-steroidal anti-inflammatory agents or analgesics. The evidence that muscle relaxants relieve pain more than placebo is weak, and the incidence of side effects like drowsiness is high. Studies of the early treatment of whiplash provide moderate evidence that early mobilisation physiotherapy[17-20] and advice to “act as usual”[21] are more effective than immobilisation and less active treatments in speeding up recovery and reducing chronic disability. Less evidence exists for the benefit of home exercise regimens,[22] pulsed electromagnetic field therapy,[23] and multimodal therapy.

Randomised controlled trials identified by systematic reviews[5-8] provide moderate evidence that various exercise regimens—using proprioceptive, strengthening, endurance, or coordination exercises—are more effective than usual care (analgesics, non-steroidal anti-inflammatory drugs, or muscle relaxants)[9 25] or stress management,[10 11] although not all studies have found exercise beneficial.[12] One randomised controlled trial found exercise plus infrared heat no more effective than transcutaneous electrical nerve stimulation plus heat at relieving pain at six weeks and six months, although both were better than heat alone.[26]

Randomised controlled trials included in systematic reviews of manual treatments (mobilisation physiotherapy or manipulation)[1, 4, 5 ,13-16] provide limited evidence that mobilisation physiotherapy[17 18] and manipulation[17] are more effective for chronic neck pain than less active treatments (drug treatment, education, counseling). However, manipulation has occasionally been associated with serious neurological complications (around 5-10 per 10 million manipulations).[27]Mobilisation, manipulation, and exercise seem to be equally effective.[19 20 28] A study comparing combined exercise and manipulation with either modality alone found the combination to be more effective at three months,[21] but no difference was seen compared with exercise alone at one and two years.[22] However, another pragmatic study found no advantage at six weeks or six months of adding manual therapy (63% of patients had mobilisation physiotherapy) or heat (shortwave diathermy) to exercise and advice.[23]Systematic reviews of weak randomised controlled trials provided no conclusive evidence about the

effectiveness of acupuncture[24] or traction[25] compared with a range of other treatments in patients with chronic neck pain. The addition of psychotherapy techniques like cognitive behavioural therapy also added little to physical or mechanical treatment alone.[26].

Cegana vatham is equated with Cervical Spondylosis in Siddha. The signs and symptoms of "CeganaVatham" is described in the texts of "Yugi vaidhya sindhamani" and "Pararaja sekaram". In "Yugi vaidhya sindhamani" the disease is described with the following symptoms: pain below neck to lowback, pain both upper limbs, weight feeling over the body, depression and giddiness, burning in the both eyes, constipation and pain felt like scorpion bite over body . In "Para raja sekaram" the disease is described with the following symptoms Pain below neck to lowback, severe pain felt in both arms and numbness with tingling in the upper limbs. Siddha system of medicine emphazises different modalities of treatments and among them drugless therapy is considered to be supreme. Varmam therapy is a non-invasive procedure especially in treating musculo-skeletal disorders and neurological disorders.

Varmam therapy refers to the treatment of injured energy centres of the body which could be located in muscles, bones, nerves, joints or veins. It belongs to varmakkalai which consists in two arts (kalai) opposed by essence: medical art (varmam) for curing injuries, and martial art. The treatment consists in locating injured point(s), pressing and massaging it (them) with an intensity which depends on injury and energy centres.The failure of standard treatment for the cervical spondylosis entails search for good treatment modalities in traditional system of medicine. It is the need of the hour to establish the non-invasive Varmam procedure for the treatment of cervical spondylosis

II. AIM

To assess the therapeutic efficacy of Varmam Procedures in the treatment of Cegana vatham.

III. TRIAL DESIGN:

Open controlled compared clinical study.

IV. PLACE OF STUDY:

Siddha Central Research Institute, Chennai.
Siddha Regional Research Institute, Trivandrum.

V. SAMPLE SIZE:

.

30 cases with Varmam application alone

VI. TREATMENT

Stimulation of the following Varmam Points

In the neck

1.	விலங்கு வர்மம்.	Viḷanku varmam
2.	காக்கட்டை வர்மம்.	Kākkattai varmam
3.	அகபுற தாரை வர்மம்,	Aka, puṛa tārai varmam
4.	கிளிமுக வர்மம்.	Kiḷimuka Varmam

In the hand

1.	கோச்சு வர்மம்.	Kōccu varmam
2.	புற தாரை வர்மம்.	Pura tārai varmam
3.	குரு நாடி வர்மம்.	Kuru nāti varmam
4.	துதிக்கை வர்மம்.	Tutikkai varmam
5.	வெள்ளை வர்மம்.	Veḷḷai varmam
6.	பெருவிரல் கவளி வர்மம்.	Peruviral kavaḷi varmam

VII. DURATION OF TREATMENT: 7 days

VIII. CRITERIA FOR INCLUSION

Corresponding to diagnostic standards of cervical spondylosis

- Patients with chief complaint of neck pain
- One or more symptoms - neck pain, neck stiffness attack one average per month for at least 3 months
- VAS scores more than 3 points at entry
- The result of antero-posterior and lateral radiogragh corresponds to x-ray diagnostic standards of cervical spondylosis, or MR/CT scan shows the degeneration of cervical spine herniation.
- Age between 18- 60 years

IX. CRITERIA FOR EXCLUSION

Corresponding to the diagnostic standards of cervical spondylosis myelopathy;

- Suffering from severe systemic diseases such as diabetes mellitus, cardio-cerebro - vascular disease, tumors and diseases that researchers consider unsuitable for research.
- Having neck trauma/fracture/surgery history, neurologic impairment (such as myasthenia or abnormal spinal nerve reflex).
- Congenital spinal abnormality, systemic diseases of bones or joints.
- Pregnant or lactation period in women.
- Receiving current treatments for cervical spondylosis (medicine or non-medicine).

X. CRITERIA FOR WITHDRAWAL

During the course of the trial there may be certain potential adverse threats and if any other side effects and other symptoms are observed then the trial drugs will be withdrawn and the patient will be treated symptomatically.

XI. METHODS OF ASSESSMENT

Clinical assessment will be done (O) and every day till the completion of treatment (Form 2). The Lab investigations (Biochemical markers) will be recorded before treatment. The X-ray will be done before and after the completion of the treatment.

XII. PERIOD OF STUDY

7 days

XIII. SUCCESS OF TREATMENT

30% or more in mobilization without pain will be considered as significant improvement. .

XV. ETHICAL REVIEW

Clearance certificate from Institutional Ethical Committee of respective institutes should be obtained. Investigator should be submitted along with patient's information sheet and informed consent form. Both these forms should be maintained in duplicate with one copy given to the patient at the time of entry to the trial.

OPEN CLINICAL TRIAL FOR CEGANA VATHAM USING VARMAM PROCEDURE

CASE RECORD FORM I - SCREENING

BEFORE TREATMENT

(ENTER √ IN THE APPROPRIATE BOX)

1. Code No. (of clinical trial) ☐
2. Centre _____
3. Name of the subject _____
4. Gender Male ☐ Female ☐
5. Date of Birth ☐☐ ☐☐ ☐☐ Age (In Yrs) ☐☐

D D M M Y Y

6. Address: Permanent postal address with phone number / e-mail, if any

CRITERIA OF INCLUSION

- Patients with chief complaint of neck pain;
- One or more symptoms - neck pain, neck stiffness attack one average per month for at least 3 months;
- VAS score more than 3 points at entry
- The result of antero-posterior and lateral radiogragh corresponds to x-ray diagnostic standards of cervical spondylosis or MRI/CT scan shows the degeneration of cervical spine.
- Age between 18~60 years

EXCLUSION CRITERIA

- Suffering from severe systemic diseases such as diabetes mellitus, cardio-cerebro-vascular disease, tumors and diseases that researchers consider unsuitable for research.

- Having neck trauma/fracture/cervical rib/surgery history, neurologic impairment (such as myasthenia or abnormal spinal nerve reflex).
- Congenital spinal abnormality, systemic diseases of bones or joints.
- Pregnant or lactation period in women.
- Receiving current treatments for cervical spondylosis (medicine or non-medicine).

A subject is eligible for admission, if 'yes' is the answer for inclusion and exclusion criteria

Date:_____ Signature of investigator:_____

OPEN CLINICAL TRIAL FOR CEGANA VATHAM USING VARMAM PROCEDURE

CASE RECORD FORM II - HISTORY

BEFORE TREATMENT

(ENTER √ IN THE APPROPRIATE BOX)

7. Code No. (of clinical trial) ☐
8. Centre _____
9. Name of the subject _____
10. Serial No. of the subject ☐
11. Gender Male ☐ Female ☐
12. Date of Birth ☐☐ ☐☐ ☐☐ Age (In Yrs) ☐☐

D D M M Y Y

13. Address: Permanent postal address with phone number / e-mail, if any

14. Educational status :(Enter √ IN THE APPROPRIATE BOX)

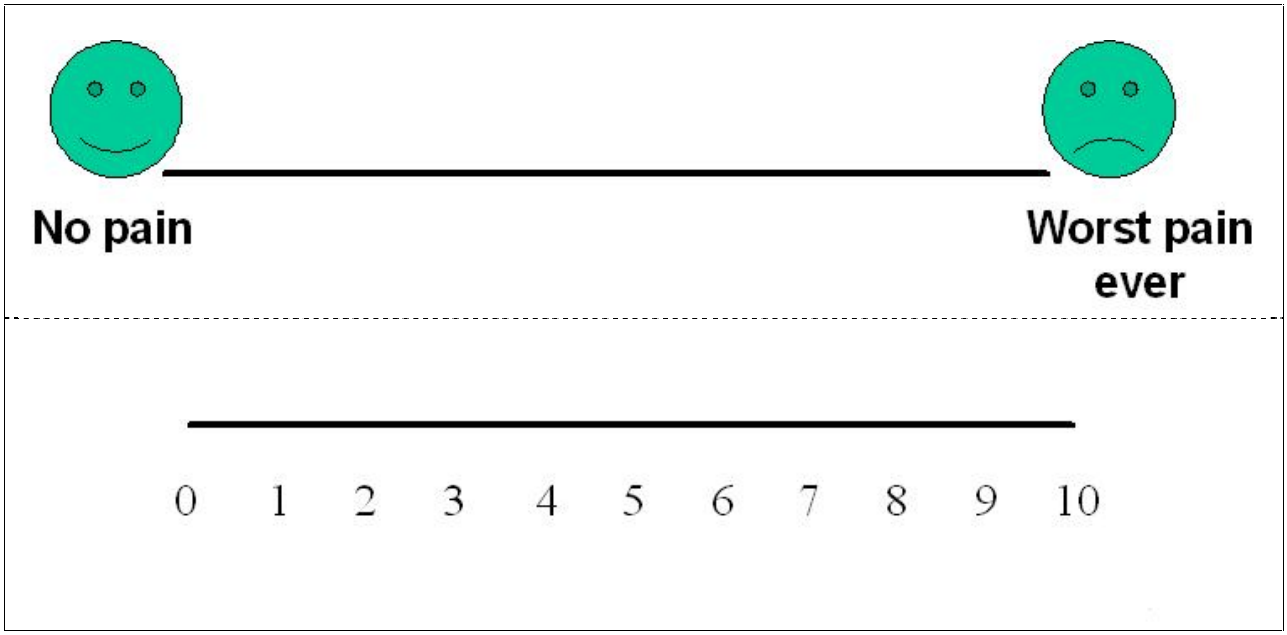
Illiterate ☐ Matriculation ☐ Graduate ☐ Postgraduate ☐

15. Annual income ☐ 60,000 (enter <, >)

16. Occupation
17. The History of previous illness and treatment ☐

18. History of present illness:

	Grade	Present/absent
▪ Pain in neck	1	☐
▪ Muscle pain restricting movements	2	☐
▪ Stiffness	3	☐
▪ Guidiness on movements	4	☐
▪ Numbness in the limbs /Fingers	5	☐
▪ Disequilibirium	6	



Duration of above registered symptoms _____ days

19. Personal history:

	YES	NO
▪ Smoking	☐	☐
▪ Alcoholic	☐	☐
▪ Non-vegetarian Diet ▪ Udaliyal	☐	☐

Vali ☐

Azhal ☐

Iyam ☐

Thontham ☐

20. Physical examination

1. Built ☐
2. Gait ☐
3. Body Weight ☐ kgs
4. Height ☐
5. BMI ☐
6. Temperature ☐
7. Blood Pressure ☐ mm/Hg
8. Pulse rate ☐ /min
9. Respiratory rate ☐ /min
10. Pallor Present ☐ ☐ Absent
11. Jaundice ☐ ☐
    ☐ ☐

12. Koilonychia

13. Lymphadenopathy ☐ ☐

Motor System

Power

Upper limb :	**Right**	**Left**
21.Shoulder (flex, ext, abd, add, rotation)	☐	☐
22.Elbow (flex, ext)	☐	☐
23.Wrist (flex, ext, pro, sup, add, abd)	☐	☐

Lower limb	**Right**	**Left**
24.Hip (flex, ext, abd, add, rotation)	☐	☐
25.Knee (flex, ext)	☐	☐
26.Ankle (dorsi & plantar flex, inv, ever)	☐	☐

Tone

27.Hypertonia ☐ 38.Hypotonia ☐

Deep tendon reflexes	**Right**	**Left**
28.Biceps (C5)	☐	☐
29.Triceps(C6,C7)	☐	☐
30.Supinator(C5, C6)	☐	☐
31. Knee(L3, L4)	☐	☐
32.Ankle(S1)	☐	☐

Superficial reflexes	**Right**	**Left**
33.Corneal / conjunctival reflex	☐	☐
34.Abdominal reflex	☐	☐
35.Cremasteric reflex	☐	☐
36.Plantar reflex	☐	☐

UYIR THATHUKKAL

VALI - ABSENT (0) NORMAL (1) DECREASED (2) INCREASED (3)

37. Uyirkkal (Pranan)

Digestion ☐ _____

38. Kizhnokkukkal (Abanan)

Excretion of Urine ☐ _____

Excretion of Faeces ☐ _____

39. Paravukal (Viyanan)

Blinking ☐ _____

Movement of limbs ☐ _____

40. Melnokkukkal (Uthanan)

Eloquence ☐ _____

Complexion ☐ _____

Hiccup ☐ _____

41. Nadukkal (Samanan)

Digestion ☐ _____

42. Nagan

Hearing ☐ _____

Thinking ☐ _____

Closing &opening of eyelids ☐ _____

43. Koorman

Winking of eyelids ☐ _____

Yawning ☐ _____

Closing of mouth ☐ _____

44. Kirukaran

Salivary secretions ☐ _____

Hunger ☐ _____

45. Devathathan

Occular Movements ☐ _____

Laziness ☐ _____

AZHAL - ABSENT (0) NORMAL (1) DECREASED (2) INCREASED (3)

46. Aakkanal (Anar pitham)

Digestion ☐ _____

47. Vannayeri(Ranjagam)

Pallor ☐ _____

48. Aattralangi(Sathagam)

Movements ☐ _____

49. Olloli Thee (Prasagam)

Complexion ☐ _____

Colour of Skin ☐ _____

Brightness of Skin ☐ _____

50. Nokkazhal(Alosagam)

Vision ☐ _____

IYAM - ABSENT (0) NORMAL (1) DECREASED (2) INCREASED (3)

51. Aliiyam (Avalambagam)

Respiration ☐ _____

52. Neerppiiyam(Kilethagam)

Digestion ☐ _____

53. Suvaikanaiyam (Pothagam)

Taste ☐ _____

54. Niraivaiyam (Tharpagam)

Cooling of eyes ☐ _____

55. Onriyaiyam (Santhigam)

Movements of joints ☐ _____

VATHAM ☐ PITHAM ☐ KABAM ☐ _____

CENTRAL COUNCIL FOR RESEARCH IN SIDDHA

OPEN CLINICAL TRIAL FOR CEGANA VATHAM USING VARMAM PROCEDURE

FORM III - LABORATORY INVESTIGATION

1. Code No. (of clinical trial) ☐

1. Centre:

3. S.No. of patients _____

4. Name of the patient _____

5. Address _____

_____

6. Gender Male ☐ (1) Female ☐ (2)

7. Date of birth ☐☐ ☐☐ ☐☐ 8. Age (Yrs) ☐☐

9. Date of assessment _____

Blood

10. TC (Cells/Cumm)_____

Differential Count

11. P (%) _____ 12. L (%) _____ 13. E (%) _____ 14. M (%) ____ 15.B (%) ___

16. Hb (g/dl) _____.

17. ESR (1/2 hour.) _____ ESR (1 hour.) _____

18. Blood Sugar- Fasting (mg/dl) _____

19. Blood Sugar – PP (mg/dl) _____

20. Blood Urea (mg/dl) _____

21. S. Creatinine (mg/dl) _____

22. Uric acid (mg/dl) _____

LIPID PROFILE

23. Serum total Cholesterol (mg/dl) _____

24. S. Triglycerides (mg/dl) _____

25. HDL (mg/dl) _____

26. LDL (mg/dl) _____

27. VLDL (mg/dl) _____

LIVER FUNCTION TESTS
Serum Bilirubin

28. Total (mg/dl) _____

29. Direct (mg/dl) _____

30. SGOT (IU/L) _____

31. SGPT (IU/L) _____

32. Alk. Phosphatase (KA units) _____

33. Total proteins (gm/dl) _____

34. Albumin (gm/dl) _____

35. Globulin (gm/dl) _____

36. A/G Ratio _____

Serum Electrolytes

37. Sodium (mEq/L) _____

38. Potassium (mEq/L) _____

39. X-RAY
Cervical spine AFFECTED JOINT – AP/LATERAL VIEW

40. CT SCAN/MRI – Cervical spine
Sl.No.10-38 & 40 will be done before treatment 39 & 40 will be done before and after treatment.
Date: _____ Signature of Doctor _____
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