



Clinical Trial Details (PDF Generation Date :- Sat, 04 Jul 2020 23:09:22 GMT)

<b>CTRI Number</b>	CTRI/2017/03/008041 [Registered on: 08/03/2017] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	04/02/2019	
<b>Post Graduate Thesis</b>	Yes	
<b>Type of Trial</b>	Interventional	
<b>Type of Study</b>	Yoga & Naturopathy	
<b>Study Design</b>	Randomized, Parallel Group, Active Controlled Trial	
<b>Public Title of Study</b>	A clinical trial to study effect Of Yoga As Add On Therapy In Migraine patients	
<b>Scientific Title of Study</b>	Effect Of Yoga As Add On Therapy In Migraine: (CONTAIN) A Randomized Controlled Study	
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>
	nil	NIL
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>	
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<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> All India Institute of medical sciences ansari nagar new delhi 110029			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
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	<b>Type of Sponsor</b>	Research institution and hospital		
<b>Details of Secondary Sponsor</b>	<b>Name</b>	<b>Address</b>		
	nil	nil		
<b>Countries of Recruitment</b>	<b>List of Countries</b>			
	India			
<b>Sites of Study</b>	<b>Name of Principal Investigator</b>	<b>Name of Site</b>	<b>Site Address</b>	<b>Phone/Fax/Email</b>
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<b>Details of Ethics Committee</b>	<b>Name of Committee</b>	<b>Approval Status</b>	<b>Date of Approval</b>	<b>Is Independent Ethics Committee?</b>
	IECPG-47/16.02.2017 AIIMS	Approved	16/02/2017	No
<b>Regulatory Clearance Status from DCGI</b>	<b>Status</b>		<b>Date</b>	
	Not Applicable		No Date Specified	
<b>Health Condition / Problems Studied</b>	<b>Health Type</b>		<b>Condition</b>	
	Patients		migraine patient	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	medication & yoga	Yoga module for migraine S.No. Exercise Rounds Time I Starting Prayer 1 1min II Breathing Exercise 1 Hands in and out breathing 5 1 min 2 Hands Stretch exercise 5 1 min 3 Ankle stretch 5 1 min 4 Straight leg raising(alternate) 10 2 min 5 Tiger breathing 5 1 min 6 Sashankasana 5 1 min III IRT 1 1 min IV Sookshma vyayama 1 Fingers, wrist, elbow, shoulder rotation, neck flexion/extension, neck rotation. 10 rounds each 15 min V Suryanamaskar 3 3 min VI QRT 1 3 min VII Asanas 1. Padahasthasana 1 min 2. Ardha chakrasana 1 min 3. paschimottanasan 1 min 4. Adho mukha svanasana 1 min 5. Setu bandhasana 1 min 6. Bhujanga 1 min 7. Vakrasana 1 min 8. Ustrasana 1 min VII Shavasana-yoga nidra or DRT	



		10min VIII Pranayama 1. kapalbhati 1 1 min 2. Nadi suddhi 10 5 min 3. bhramari 5 1 min 4. nadanusandhana 5 min 5. Cooling exercises-sitali,sitkari and sadanta 15 3 min TOTAL 60 min
	Comparator Agent	medicine only previously used prophylactic medication for migraine
<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>	
	<b>Age From</b>	18.00 Year(s)
	<b>Age To</b>	50.00 Year(s)
	<b>Gender</b>	Both
	<b>Details</b>	<ol style="list-style-type: none"> <li>1. Patients aged 18-50 years</li> <li>2. Written informed consent from participants</li> <li>3. A clinical diagnosis of migraine with or without aura using ICHD-III- beta 2013 criteria</li> <li>4. Headache frequency ? 4 per month but 14 migraine /month or</li> <li>5. Any other prior neurological disease like head trauma, dementia, seizure, encephalitis, meningitis, stroke.</li> <li>6. Any other significant co-morbidity that clinician deems unfit for participation in the study.</li> </ol>
<b>Method of Generating Random Sequence</b>	Computer generated randomization	
<b>Method of Concealment</b>	Sequentially numbered, sealed, opaque envelopes	
<b>Blinding/Masking</b>	Participant and Outcome Assessor Blinded	
<b>Primary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	<ol style="list-style-type: none"> <li>1. Change in headache frequency and intensity</li> <li>2. Change in Headache impact test (HIT-6) score</li> </ol>	3 months
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	<ol style="list-style-type: none"> <li>1. Proportion of patients who become headache free</li> <li>2. Medication score by counting numbers of analgesic pills used over the prophylactic drugs</li> <li>3. Improvement in MIDAS score using MIDAS questionnaire</li> </ol>	6 months
<b>Target Sample Size</b>	<b>Total Sample Size=160</b> <b>Sample Size from India=160</b> <b>Final Enrollment numbers achieved (Total)=160</b> <b>Final Enrollment numbers achieved (India)=160</b>	
<b>Phase of Trial</b>	N/A	
<b>Date of First Enrollment (India)</b>	03/04/2017	
<b>Date of First Enrollment (Global)</b>	No Date Specified	
<b>Estimated Duration of Trial</b>	<b>Years=1</b> <b>Months=0</b> <b>Days=0</b>	
<b>Recruitment Status of Trial (Global)</b>	Not Applicable	



<b>Recruitment Status of Trial (India)</b>	Completed
<b>Publication Details</b>	not yet
<b>Brief Summary</b>	<p style="text-align: center;"><b>Title: EFFECT OF YOGA AS ADD ON THERAPY IN MIGRAINE: (CONTAIN). A RANDOMIZED CONTROLLED STUDY</b></p> <p><b>Introduction</b></p> <p>Headaches are a common clinical phenomenon among humans. They have been suggested as the main cause of time off from work, reduced school performance, and low quality of life.<sup>1-3</sup> Furthermore, they have led to personal, familial and societal burdens, and significant healthcare problems globally.<sup>4,5</sup></p> <p>Migraine is one of the common primary headache disorders affecting 13% of the population worldwide.<sup>6</sup> Prodromal, headache episode and postdromal phases of migraine are known to impact productivity at work and quality of life, apart from causing cognitive impairment.<sup>7</sup></p> <p>Migraine clinically manifests as an hemicranial throbbing type of pain associated with nausea, vomiting, heightened sensitivity to light (photophobia) and sound (phonophobia) with or without transient neurological symptoms.<sup>8</sup></p> <p>It is also a risk factor for ischemic cerebral and ischemic cardiovascular diseases. Episodic migraine may lead to chronic migraine, if it is not treated properly it may lead to medication overuse headache and increased risk of suicidal attempt.<sup>9</sup></p> <p>Traditionally, medications are first-line treatment for migraine therapy. However, only about half of migraineurs have clinically meaningful responses to preventive drug treatments, more than 10% discontinue due to adverse events,<sup>10</sup> and half report dissatisfaction with their current treatment strategies.<sup>11</sup> When preventive treatments are ineffective, migraineurs may overuse symptomatic relief medications with a consequent worsening of their headache burden. Excessive use of abortive medications can cause the challenging and often refractory condition of medication overuse headache (MOH). These shortcomings of existing treatment options substantiate the great need for additional migraine treatment strategies.<sup>12</sup></p> <p>Yoga is one of the commonest forms of complementary and alternative medicine therapies, which is increasingly being practiced worldwide. It is an ancient Indian practice with its roots in Hindu religion based on the principles of mind-body medicine. The word “yoga” comes from the Sanskrit “yuj,” meaning “yoke” or “union.” The three essential elements of yoga are: asanas (postures), pranayama (breathing exercises), and dhyana (meditation)<sup>13</sup> Yoga has been observed to have a beneficial effect on various migraine parameters (frequency, intensity, duration of attack, medication score, and the nature of the pain<sup>14,15</sup>). The aim of this study to assess the effectiveness of yoga exercises in the management of migraine.</p> <p><b>Review of Literature</b></p>



*Kisan and colleagues*<sup>5</sup> tried to evaluate the efficacy of Yoga as an adjuvant therapy in migraine patients by assessing clinical outcome and autonomic functions tests. Sixty patients were recruited from a tertiary referral neurology centre. Significant reductions in monthly headache frequency, average pain intensity, and headache-related disability were seen in both the Yoga and Conventional Care (CC) groups. However, the yoga group showed improvement in all clinical outcome measures to a greater extent. Significant reduction in the frequency of headache were observed in the yoga group Yoga (Y) compared to CC group. At baseline, headache intensity was  $9.30 \pm 1.15$  and  $8.70 \pm 1.26$  in Group CC and Group Y respectively which reduced to  $7.73 \pm 1.23$  and  $2.03 \pm 1.29$  respectively.

*Boroujeni MZ and colleagues*<sup>16</sup> studied yoga intervention on blood NO in female migraineurs. This study was a randomized, controlled trial conducted at the Physiology Research Centre, University of Medical Sciences, Isfahan, Iran, from April to June 2012. When compared yoga and control groups after 12 weeks, the results showed a reduction in headache severity, frequency, and headache impact on patients' lives after the intervention in the yoga group; however, the changes in the control group were not significant. A non-significant increase was seen in blood NO level in both groups after treatment.

In a randomized, controlled trial comparing yoga group with a self-care group conducted at NMP Medical research Institute, a nonprofit, integrated health care clinic and under the auspices of the Department of Zoology, University of Rajasthan, India, the authors observed a statistically significant reduction in the frequency, intensity (most pain, lowest pain, average pain), duration of attack, medication score following three months of yoga intervention ( $P > .05$ ).

Wells and colleagues<sup>17</sup> conducted a pilot randomized controlled trial to study the effect of meditation for migraines. 19 episodic migraineurs were randomized to either Mindfulness-based stress reduction (MBSR) ( $n = 10$ ) or usual care ( $n = 9$ ). MBSR, It teaches mindfulness meditation and yoga, and daily assignments are used to build each participant's mindfulness practice. Primary outcome was change in migraine frequency from baseline to initial follow-up. Secondary outcomes included change in headache severity, duration, self-efficacy, perceived stress, migraine-related disability/impact, anxiety, depression, mindfulness, and quality of life from baseline to initial follow-up. From baseline to initial follow-up, compared to control, MBSR participants had fewer migraines/month ( $3.5$  to  $1.0$  migraines/month in MBSR vs  $1.2$  to  $0$  migraines/month in control, 95% confidence interval). The severity and duration of all headaches decreased in the MBSR group in comparison to control group.

**Table :** Published study characteristics and outcomes.

Study	Design	Subjects	Groups	Duration	Result/ Conclusion
Kisan R et al. <sup>5</sup>	A randomized, controlled trial	60 patients were recruited from a tertiary referral	Conventional care (Group CC) ( $n = 30$ ) or Yoga with	6 weeks	HIT score , group CC $75.43 \pm 0.9$ post $68.6 \pm 4.6$ compared to group Y $66.60 \pm 3.21$ post



	neurology centre	conventional care (n = 30). Group Y)	88.9±2.2). headache intensity was, CC 9.30 ± 1.15 post 6 week 7.73 ± 1.23 and , Y 8.70 ± 1.26 post 6 weeks 2.03 ± 1.29 Headache frequency (per/month) CC 10.5± 3.8 post 5.2±2.1 , Y 11.3 ±5.1 1.8±1.5
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Study	Design	Subjects	Groups	Duration	Re	Co
Boroujeni MZ et al. <sup>16</sup>	A randomized, controlled trial	23 female patients with migraine	The control group (n = 14) yoga group (n = 18)	12 weeks	He	Co
John et al,2007 <sup>15</sup>	Randomized controlled trial	72 migraine patients without aura	yoga vs. self-care	3 months	He	Co



					3.2 Me 2.6 1.3 2.9 3.9
Wells RE et al. <sup>17</sup>	randomized controlled trial	19	MBSR  (mindfulness based stress reduction) group (n = 10) or usual care (n = 9)	8-week	Mig MB o 1 Co 1.2 He 0- MB 3.2 gro Co 5.2 He s) 2.9 Co Co 5.1



## Hypothesis:

Yoga as an adjunctive therapy to medical management is superior to medical management alone in patients with migraine headaches.

## Aims

1. To evaluate the efficacy of yoga as an adjunct to conventional medical management on clinical outcome in patients with migraine.

## Objectives:

### *Primary*

1. To observe if add on treatment with Yoga to conventional medical therapy results in Improvement in headache frequency and intensity.
2. To observe if add on treatment with Yoga to conventional medical therapy results in Improvement in headache impact test (HIT-6) score

### *Secondary*

1. To observe if add on treatment with Yoga to conventional medical therapy results in higher Proportion of patients who become headache free
  2. To observe if add on treatment with Yoga to conventional medical therapy results in Reduction in use of rescue medications for acute headache management.
  3. To observe if add on treatment with Yoga to conventional medical therapy results in Improvement in MIDAS score using MIDAS questionnaire.



## Methods

### Patient population

All patients with diagnosis of migraine using **ICHD- III- beta 2013** criteria, visiting the Neurology outpatient clinic at the Neurosciences centre, AIIMS.

### Inclusion criteria

- Patients aged 18-50 years
- Written informed consent from participants
- A clinical diagnosis of migraine with or without aura using **ICHD- III- beta 2013** criteria
- Headache frequency ? 4 per month but <14 per month
- Residing in Delhi-NCR.
- No contraindications for yoga therapy
- if patients on drug prophylaxis; no change of drug for at least three months and no change of dose for at least one month prior to enrolment

### Exclusion criteria

- Denied informed consent.
- Any contraindications for yoga therapy
- Enrolled in any other trial.
- >14 migraine /month or < 4 migraine/ month
- Any other prior neurological disease like head trauma, dementia, seizure, encephalitis, meningitis, stroke.
- Any other significant co-morbidity that clinician deems unfit for participation in the study.



### Study design

Randomized Controlled Trial with blinded endpoint assessment.

### Sample size calculation (n=160):

From previous study Kisan R et al<sup>5</sup> change in headache frequency was intervention group  $5.66 \pm 4.44$  versus  $3.06 \pm 4.5$ . Using these results the sample size would be 12 per group with 5% two sided alpha error and 90% power. While HIT-6 score after 3 month yoga intervention was  $67 \pm 18$  as compared control group  $75 \pm 5$ . taking this same as a expected result in our study we required 58 subjects in each groups to detect the difference to be statistically significant with 5% alpha error and 90 % power. Assuming 25% losses in the follow up we required 78 per group. Accordingly 160 patients will be randomized.

**Randomisation:** Computer Generated and Block randomization with variable block size. Randomization list will be transferred to sealed envelop and each envelop will be open when corresponding number of eligible participant will be enrolled.

### Intervention details

Following an informed consent, the eligible patients will be randomly recruited into either of the two groups: control group (Conventional medical management) and the experimental group (Yoga+ conventional medical management). Each subject will be treated with appropriate medical therapy as deemed suitable by the treating neurologist. Each subject will be counselled about lifestyle modification including appropriate sleep, regular meals, mental relaxation and a regular physical activity schedule as suitable to him/her. The intervention will be an Integrated Yoga module that has been standardised earlier in addition to the conventional medical management for migraine. In the yoga intervention group, the yoga regimen will consist of the following schedule as mentioned in table 1. This will be 3 days/week for 1 month at CIMR followed by 5 days/week for 3 months at home. A booklet containing the details of the practice will be given to the participants and the patients can clarify their doubts through phone or by visiting the centre located in AIIMS. Compliance will be ensured telephonically and by a daily log maintained by the patient.

### Follow up

Each subject will be followed up once at the end of 1, 2 and 3 months for assessment of the clinical status, At each visit he will be assessed on the outcome parameters as below. 6 months follow up will be used to ascertain sustained long term benefit between the two groups.

### Outcome parameters.

#### Co-Primary outcomes:

1. Change in headache frequency and intensity
2. Change in Headache impact test (HIT-6) score



**Secondary outcomes:**

1. Proportion of patients who become headache free
2. Medication score by counting numbers of analgesic pills used over the prophylactic drugs
3. Improvement in MIDAS score using MIDAS questionnaire

Each patient will be asked to maintain a headache diary. Details of the attacks will be recorded to assess for the frequency, intensity, need for rescue analgesic therapy or any other specific complaints. The severity of headache will be assessed using the visual analogue scale (recorded from 0-10, appendix). The change in headache specific disability indices for improvement will be assessed using MIDAS (Migraine Disability Assessment questionnaire), and Headache impact test (HIT).

**The visual analogue scale or visual analogue scale (VAS)** is a [psychometric](#) response scale. It is a measurement instrument for subjective characteristics or attitudes that cannot be directly measured. When responding to a VAS item, respondents specify their level of agreement to a statement by indicating a position along a continuous line between two end-points.

**MIDAS (Migraine Disability Assessment questionnaire)**

The Migraine Disability Assessment (MIDAS) questionnaire is a brief, self-administered questionnaire designed to quantify headache-related disability. The MIDAS score has been shown to have moderately high test-retest reliability in headache sufferers and is correlated with clinical judgment regarding the need for medical care. The Migraine Disability Assessment (MIDAS) questionnaire was developed to measure the effect [headaches](#) have on a person's daily functioning. MIDAS takes into account the past three months and is composed of five questions -- simple and short.

**Headache impact test (HIT)**

The Headache Impact Test-6 (HIT-6) measures a wide spectrum of the factors contributing to the burden of headache. The HIT-6 consists of six items: pain, social functioning, role functioning, vitality, cognitive functioning, and psychological distress. The patient answers each of the six related questions using one of the following five responses: "never", "rarely", "sometimes", "very often", or "always". These responses are summed to produce a total HIT-6 score that ranges from 36 to 78, where a higher score indicates a greater impact of headache on the daily life of the respondent.

**Migraine diary**

Using a self-administered diary, participants were asked to report information on the start and stop time of any headache, headache-specific characteristics and symptoms, and use of any acute headache pain medication.

**Possible adverse effects:**

1. **Due to drugs:** nausea, vomiting , abdominal discomfort, giddiness, blurring of vision, any



skin reaction or any allergy , any serious adverse effect

**2. Due to yoga intervention:** sprain , any ligament or muscle injury, joint dislocation or any serious adverse effect

**Statistical analysis**

The changes in headache frequency, intensity, HIT-6 score, MIDAS score and proportion of patient become headache free were compared between baseline and yoga intervention groups by using t-test / rank sum test

**Expected Outcome of the study:**

The proposed study is a first of its kind comprehensive study, which aims to understand the effect of Integrated Yoga practices on the overall morbidity and mortality of patients with migraine. We speculate that the proposed study will be helpful in identifying the pathways that facilitates adaptation and well-being.

Yoga module for migraine				
S.No.	Exercise	Rounds	Time	
	Starting Prayer	1	1 min	
1	Breathing Exercise			
1	Hands in and out breathing	5	1 min	
2	Hands Stretch exercise	5	1 min	
3	Ankle stretch	5	1 min	
4	Straight leg raising(alternate)	10	2 min	
5	Tiger breathing	5	1 min	
6	Sashankasana	5	1 min	



II	RT	1	1 min
V	Sookshma vyayama		
1.	Fingers, wrist, elbow, shoulder rotation, neck flexion/extension, neck rotation.	10 rounds each	15 min
V	Suryanamaskar	3	3 min
VI	QRT	1	3 min
VII	Asanas		
1.	Padahasthasana		1 min
2.	Ardha chakrasana		1 min
3.	paschimottanasan		1 min
4.	Adho mukha svanasana		1 min
5.	Setu bandhasana		1 min
6.	Bhujanga		1 min
7.	Vakrasana		1 min
8.	Ustrasana		1 min
VII	Shavasana-yoga nidra or DRT		10min
VIII	Pranayama		
1.	kapalbhati	1	1 min
2.	Nadi suddhi	10	5 min
3.	ohramari	5	1 min



4.	Shadanasandhana		5 min
5.	Cooling exercises-sitali,sitkari and sadanta	15	3 min
	TOTAL		60 min

## HIT-6™

This questionnaire was designed to help you describe and communicate the way you feel and what you cannot do because of headaches.

HIT-6™ Headache Impact Test

To complete, please circle one answer for each question.

1. When you have headaches, how often is the pain severe?

never rarely sometimes very often always

2. How often do headaches limit your ability to do usual daily activities including household work, work, school, or social activities?

never rarely sometimes very often always

3. When you have a headache, how often do you wish you could lie down?

never rarely sometimes very often always

4. In the past 4 weeks, how often have you felt too tired to do work or daily activities because of your headaches?

never rarely sometimes very often always

5. In the past 4 weeks, how often have you felt fed up or irritated because of your headaches?

never rarely sometimes very often always

6. In the past 4 weeks, how often did headaches limit your ability to concentrate on work or daily activities?

never rarely sometimes very often always

COLUMN 1: 6 points each



COLUMN 2: 8 points each

COLUMN 3: 10 points each

COLUMN 4: 11 points each

COLUMN 5: 13 points each

**If your HIT-6 is 50 or higher:** You should share your results with your doctor. Headaches that stop you from enjoying the important things in life, like family, work, school or social activities could be migraine.

**TOTAL SCORE:**

## **DIAGNOSTIC CRITERIA OF MIGRANE-**

**According to International Classification of Headache Disorders (ICHD- III- beta, 2013)**

### **1.1 Migraine without aura**

**Diagnostic criteria:**

A. At least five attacks fulfilling criteria B–D

B. Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated)

C. Headache has at least two of the following four characteristics:

1. Unilateral location

2. Pulsating quality



3. Moderate or severe pain intensity
  4. Aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs)
- D. During headache at least one of the following:
1. Nausea and/or vomiting
  2. Photophobia and phonophobia
- E. Not better accounted for by another ICHD-3 diagnosis.

## 1.2 Migraine with aura

### Diagnostic criteria:

- A. At least two attacks fulfilling criteria B and C
- B. One or more of the following fully reversible aura symptoms:
1. Visual
  2. Sensory
  3. Speech and/or language
  4. Motor
  5. Brainstem
  6. Retinal
- C. At least two of the following four characteristics:
1. At least one aura symptom spreads gradually over 5 minutes, and/or two or more
- Symptoms occur in succession
2. Each individual aura symptom lasts 5-60 minutes



- 3. At least one aura symptom is unilateral
  - 4. The aura is accompanied, or followed within 60minutes, by headache
- D. Not better accounted for by another ICHD-3 diagnosis, and transient ischemic attack has been excluded.

**The Migraine Disability Assessment Test**

The MIDAS (Migraine Disability Assessment) questionnaire was put together to help you measure the impact your headaches have on your life. The information on this questionnaire is also helpful for your primary care provider to determine the level of pain and disability caused by your headaches and to find the best treatment for you.

**INSTRUCTIONS**

Please answer the following questions about ALL of the headaches you have had over the last 3 months. Select your answer in the box next to each question. Select zero if you did not have the activity in the last 3 months. Please take the completed form to your healthcare professional.

\_\_\_ 1. On how many days in the last 3 months did you miss work or school because of your headaches?

\_\_\_ 2. How many days in the last 3 months was your productivity at work or school reduced by half or more because of your headaches? (Do not include days you counted in question 1 where you missed work or school.)

\_\_\_ 3. On how many days in the last 3 months did you not do household work (such as housework, home repairs and maintenance, shopping, caring for children and relatives) because of your headaches?

\_\_\_ 4. How many days in the last 3 months was your productivity in household work reduced by half or more because of your headaches? (Do not include days you counted in question 3 where you did not do household work.)

\_\_\_ 5. On how many days in the last 3 months did you miss family, social or leisure activities because of your headaches?

Total (Questions 1-5)

**What your Physician will need to know about your headache:**

\_\_\_ A. On how many days in the last 3 months did you have a headache? (If a headache lasted more than 1 day, count each day.)

\_\_\_ B. On a scale of 0 - 10, on average how painful were these headaches? (where 0=no pain at all, and 10= pain as bad as it can be.)

**Scoring:** After you have filled out this questionnaire, add the total number of days from questions 1-5 (ignore A and B). (If Your MIDAS Score is 6 or more, please discuss this with your doctor.)

MIDAS Grade	Definition	MIDAS Score



	Little or No Disability	0-5	
I	Mild Disability	6-10	
II	Moderate Disability	11-20	
V	Severe Disability	21+	

## Patient Information Sheet

You are being invited to participate in a research study. This form is designed to provide you with information about this study. The Principle investigator or representative will describe this study to you and answer any of questions. If you have any questions or complaints about the informed consent process or the research study, please contact the Institutional Ethical Committee.

**Title of the Study/Project:** Effect of yoga as add on therapy in migraine (**CONTAIN**): A randomized controlled study”.

### Methods of the research:

You have been diagnosed by your doctor as a case of headache disorder known as Migraine. You will be treated by an appropriate medication as decided by your doctor for a better control of your headaches. This study wants to see whether Yoga therapy along with medical treatment is better than medical treatment alone. In case you wish to participate you will be assigned to one of the two treatment groups randomly: Yoga and medication group ( herein called the intervention group) or only medication group. If you are recruited to the medical treatment group, you will be required to take standard medication along with lifestyle modification and regular exercise and on recruitment to the Yoga group, you shall practice Yoga regularly along with the medication and lifestyle modifications.

On volunteering to participate in the intervention group i.e., participating in the Yoga group, you are required to attend Yoga practice sessions three days a week for 1 hour each for a total duration of 4 weeks at the AIIMS center for integrative medicine and research (CIMR) and then practice yoga regularly at home thereafter for 5 months. The practice shall comprise of asana (physical postures), pranayama (voluntary breath regulation), dhyana (meditation), relaxation and kriya (cleansing) practices. The practices will be administered by trained Yoga teachers.

You will be required for regular follow-up visits at 1 month, 2 month, 3, and 6 months.. You will be asked to maintain a diary record of your headaches and



will be asked questions on your follow up visits about the control of your symptoms and how you have been feeling overall.

**Expected duration of participation:**

The initial period of regular follow up is for three months. You will be requested to come for a review at 6 months also. You are free to come and visit your doctor for any need in between also depending upon your clinical condition.

**The benefits to be expected from the research to the subject or to others:**

Both Yoga practices & Life style modifications have been shown to be beneficial. Hence, it might have a positive implication on your headache control and overall health status.

**Any risk to the subject associated with the study:**

There are no known risk factors following Yoga practices. You will be taught yoga exercises for the first one month under close supervision. However, if in case there is any accidental injury or any physical problem while practicing Yoga, immediate medical care will be provided at AIIMS, New Delhi.

**Maintenance of confidentiality of records:**

AIIMS, New Delhi will protect the confidentiality of your records to the extent provided by Law. You understand that the study investigators and the Institutional Ethics Committee have the right to review your records.

**Provision of free treatment for research related injury:**

In case of any injury first aid measures will be provided free of cost.

**Compensation of subjects for disability or death resulting from such injury:**

No complications have been recorded due to practice of Yoga. Death or disability has due to Yoga practice is not likely. In the unlikely event of your sustaining



a physical injury arising out of this study, primary care will be provided at the research center without charge.

Since, participation in this study is purely voluntary and if you choose to participate, you are free to withdraw your consent and discontinue participation in this research study at any time by giving it in writing without this decision affecting your medical care and health insurance provided to you during the study. If you have any question regarding your rights as a subject, you may phone the Institutional Ethics Committee office.

**Costs and source of investigations, disposables, implants and drugs / contrast media must be mentioned.**

You are not required to pay any cost for the investigations or classes that you are offered during your participation in the study. The cost will be borne by the funds received for research. No physical implants or contrast media

If you have any queries regarding the project, you can call the Investigators at the numbers given below.

**Dr. Anand Kumar**

Senior resident

Neurology

AIIMS

Ph:9454147848

**Dr. Rohit Bhatia**

Professor

Neurology

AIIMS

ph: 011-26546625



## Informed Consent Form

Protocol / Study number: \_\_\_\_\_

Patient identification number for this trial: \_\_\_\_\_

**Title of project: "Effect of yoga as add on therapy in migraine(CONTAIN): A randomized controlled study"**

Name of Principal Investigator:

Dr. Anand Kumar

Dr. Rohit Bhatia

The contents of the information sheet dated.....(Version)..... That was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from department of neurology, AIIMS or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

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Date:

(Signature / Left Thumb Impression)

Place:

Name of the Participant: \_\_\_\_\_

Son / Daughter / Spouse of: \_\_\_\_\_

Complete postal address: \_\_\_\_\_

This is to certify that the above consent has been obtained in my presence.

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Signature of the Principal Investigator

Date:

Place:

1) Witness – 1

2) Witness – 2

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Signature

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Signature

Name:

Name:

Address:

Address:

Phone :Dr. Anand Kumar 9454147848

Dr. Rohit Bhatia 9891267417