Acta Scientific Neurology (ISSN: 2582-1121)

Volume 3 Issue 6 June 2020

Research Article

A Study Protocol to Evaluate Effect of Yoga in People with Epilepsy

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Received: April 05, 2020

Published: May 28, 2020

Abstract

Introduction: Epilepsy is a disorder in which recurrent seizures are caused by abnormal electrical discharges in the brain. As there are many Non-pharmacological remedies tried to evaluate their impact on the Epilepsy and Seizure and on Quality Life of People with Epilepsy. However, there is no conclusive data has been published to establish the positive impact of non-pharmacological intervention on Epilepsy or related quality of life. As there is lack of randomized trials on effect of Yoga on Epilepsy, we designed this study to evaluate the effect of Yoga on EEG, WHOQOL-brief and seizure frequency.

Methodology: This is prospective, single centre, Double blinded randomized control trial, and the individual assessing the pre and post values of the patients is blinded to which group the patient belongs and at the same time the yoga instructor is blinded to the pre and post assessment values of the subjects. Total 50 patients will be randomized in to interventional and control group in 1:1 ratio. WHOQOL BREF, Seizure frequency, EEG changes will be the outcome measures seen Pre inclusion, after 3 months and after 6 months for the subjects based on inclusion exclusion criteria.

Discussion: If effective, yoga may be used as an adjunct to pharmacotherapy for treatment of non-refractory epilepsy.

Conclusion: This study will put light on the benefits of Yoga if any improvement is seen in quality of life, EEG findings and seizure frequency.

Keywords: Yoga; Refractory Epilepsy; EEG; WHOQOL; Protocol

Introduction

Epilepsy is a disorder in which recurrent seizures are caused by abnormal electrical discharges in the brain. Most seizures can be controlled by antiepileptic drugs (AEDs) but sometimes seizures develop which are resistant to those drugs. People may also wish to try non-drug treatments such as yoga. Between 25% and 40% of people with epilepsy treated with AEDs have uncontrolled seizures, experience adverse effects from medication, suffer from stigmatization and have a higher degree of psychiatric disorders as compared with people with other chronic illnesses. For those who have epilepsy and related problems it is important to develop, evaluate, and implement a complementary treatment model in the everyday treatment of epilepsy.

As there are many Non-pharmacological remedies tried to evaluate their impact on the Epilepsy and Seizure and on Quality Life of People with Epilepsy. However, there is no conclusive data has been published to establish the positive impact of non-pharmacological intervention on Epilepsy or related quality of life.

Yoga, an integral part of Indian culture and heritage, is said to bestow good health - physical, mental and spiritual - on the practitioner. There are various types of yoga involving postural exercises (asanas), breath control (pranayama) and meditation. In one study, the practice of Sahaja yoga, a simple form of meditation, reduced seizures and EEG changes in people with epilepsy [1].

As there is lack of randomized trials on effect of Yoga on Epilepsy. We designed this study to evaluate the effect of Yoga on EEG, WHOQOL-brief and seizure frequency.

Rationale to explain the effects of yoga on diseases with overlapping pathophysiologies based on the principle that yoga practices reduce allostatic stress in stress response systems and restore optimal homeostasis. We assume that stress causes:

1. An imbalance of autonomy nervous system (ANS) with reduced parasympathetic nervousness the system (PNS) increased the activity of the sympathetic nervous system (SNS)
2. The activity of the inhibitory neurotransmitter, gamma-aminobutyric acid (GABA) and
3. Increased allostatic load. Yoga practices
4. Are also supposed to correct inappropriate activity PNS and GABA system in part due to vagus nerve stimulation the nerves and
5. Reduce the allostatic load, causing relief of symptoms.

Depression, epilepsy, post-traumatic stress disorder (PTSD) and chronic pain illustrates conditions exacerbated by stress, have low PNS and low GABA activity, respond to pharmacological agents that increase GABA activity and improve in response to yoga-based interventions. It is proposed Yoga-based interventions support a return to optimal balance in PNS and GABA, function is improving in regions [2].

The brain that regulates response to threats, such as threat perception, capture, fear processing, emotion regulation and defense responses. As regulatory systems become increasingly central balanced and flexible, the allostatic load is reduced, leading to health improvements.

Methodology and Result

Study design

This is prospective, single centre, Double blinded randomized control trial, the individual assessing the pre and post values of the patients is blinded to which group the patient belongs and at the same time the yoga instructor is blinded to the pre and post assessment values of the patient.

Patients

Total 50 patients will be randomized in to interventional and control group in 1:1 ratio. Adult patients from 18 to 50 years who is known Epileptic and will provide the consent will be included into the study. The patient on 1 or more AEDs with changes in EEG (refractory Epilepsy) will be included into study. The patients with physical and cognitive comorbidities will be excluded from the study.

Materials and Methods

This is prospective randomized double blinded study to assess the effects on yoga in Epilepsy Patients. The randomization of the patients will be done by random number generated through excel based tool. For effective blinding the assessors will be blinded to the group of patients, the Yoga experts will be blinded to randomization, pre and post assessment of the patients. The study duration will be 180 days.

The patients at baseline will be evaluated for Demographics, Geographic, Epilepsy History, AED history, Seizure frequency. At baseline patient will be going through baseline EEG, WHO Quality of Life Scale (WHOQOL). The EEG, WHOQOL and Seizure frequency will be evaluated by at Baseline, at 90th day and at 180th day.

The patients in interventional group will perform 11 Yogas for duration of one hour. First, they will get a training on Yoga from Yoga expert. Once they understood the procedure they will perform the Yoga once in week under supervision of Yoga expert and 5 times in week they will do the same yoga at home. For keeping a watch on compliance, the councillors will call every patient twice a week.

The panned Yoga schedule is

1. Warm up (5 minutes)
2. Suryanamaskar (10 minutes)
3. Bhamree/bhamree advance (10 minutes)
4. Mudrasan (5 minutes)
5. Matyasana (5 minutes)
6. Pavanmuktasana (5 minutes)
7. Paschimottasana (5 minutes)
8. Yin asan (5 minutes)
9. Shirshasana/sarvangasana (2 minutes)
10. Vrkshasan/dhyanasan (3 minutes)
11. Shavasana (5 minutes)

Schedule of assessments

Follow up: Follow up will be done by calling patients twice in week.

Study Period	Interventions
Days	
Day 0	Demographic, Geographical, History of Epilepsy, AEDs History, EEG, WHOQOL and Seizure frequency evaluation
Day 90	EEG, WHOQOL and Seizure frequency evaluation
Day 180	EEG, WHOQOL and Seizure frequency evaluation

Table

End points

Primary end point

To evaluate the impact of Yoga on EEG and WHOQOL.

Secondary end point

To evaluate the impact of Yoga in Seizure Frequency and other psychological parameters such as anxiety, seizure worry.

Discontinuation or withdrawal of patients

Patients who discontinue from the study treatment after enrolment and prior to the completion of the study will be required to complete the end-of-treatment assessments within one week of discontinuation/termination.

Patients will be discontinued from the study for the following reasons:

- Patients for whom the study intervention is discontinued and cannot proceed due to abnormal change of the patient's examination result or any other reasons given by the Investigator.
- The patient develops unacceptable or intolerable toxicity to the study intervention.
- The patient develops any other illness that prevents the continuation of therapy or regular study evaluations.
- The inability of the patient to comply with the protocol/study schedule in the opinion of the Investigator.

Efficacy measurement

WHOQOL-Brief

The WHOQOL-BREF produces a quality of life profile. We will derive four domain scores. We will examine two items separately: question 1 asks about an individual Zs overall perception of quality of life and question 2 asks about an individual Zs overall perception of their health. The four domain scores will denote an individual Zs perception of quality of life in each particular domain. Domain scores are scaled in a positive direction (i.e. higher scores denote higher quality of life). The mean score of items within each domain is used to calculate the domain score. Mean scores are then multiplied by 4 in order to make domain scores comparable with the scores used in the WHOQOL-100.

Seizure frequency

The Seizure frequency will be calculated by mean seizures/3 month at Baseline and 90 days and at 180 days in control and interventional group. Then relative reduction will be calculated in control and interventional group by using SPSS.

EEG changes

EEG will be recorded using a 24-channel video EEG machine during awake state and in natural sleep. EEG will be classified as normal or abnormal by a trained neurologist. When a seizure happens during an EEG, the normal pattern of brain activity that is seen on the EEG reading changes and different brain activity can be seen. In focal seizures the change in brain activity can be seen only on the electrodes on the part of the brain the seizure is happening in. The changes seen after 1 year will be noted in the alpha, beta, gamma and delta areas of EEG.

Ethics and regulatory considerations

Regulatory approval

The study will be conducted in accordance with the regulatory requirements in India - The New Drugs and Clinical Trials Rules 2019 of CDSCO (Central Drugs Standard Control Organization), Ministry of health and family welfare, Government of India; the ethical guidelines for biomedical research on human participants, ICMR (Indian Council of Medical Research (2017) and international guidelines ICH E6 (R2) 'Guideline for Good Clinical Practice' and Declaration of Helsinki (2013).

Ethical review

Institutional Ethics Committee (IEC)/Review Board's (IRB) approval will be sought at each participating centre, prior to the initiation of the study.

Informed consent procedure

Written informed consent and documentation of the procedure is mandated to be performed prior to initiating any study-related procedure. The Investigator should ensure that the consent has been properly obtained per current Indian regulations i.e. The Indian GCP and The New Drugs and Clinical Trials Rules, 2019.

Study monitoring and quality control

Audits and inspections

The Investigator should agree to permit study-related monitoring and inspections by the Independent Ethics Committee (IEC)/Institutional Review Board (IRB), Regulatory Authorities and auditing by Quality assurance groups/auditors authorized by Sponsor/designee, for all study-related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc).

Quality assurance

To ensure accurate, complete and reliable data, the Investigator will involve supervisors to monitor on timely basis.

Discussion

Refractory epilepsy is a prevalent disorder which has various social and psychological co-morbidities. These prevent these patients with refractory epilepsy from participating in normal day to day activities. Despite yoga being an adjunctive therapy for treatment of epilepsy, there isn't sufficient literature which supports this therapy. Hence we aim at studying whether yoga along with pharmacological therapy or is it only the pharmacotherapy that helps in patients with refractory epilepsy. The strength of this study includes, sample size, blinding, presence of control group; follow up at regular intervals, intervention in regular practice, and intervention for a longer duration also.

Conclusion

This study will help in providing evidence if there is any beneficial effect of YOGA on the people with refractory epilepsy with respect to quality of life, EEG changes and seizure frequency. Refractory epilepsy has serious psychological and social co morbidities and finding effective therapies to tackle it will be fruitful in reducing these comorbidities.

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