

## **A RANDOMISED CLINICAL TRIAL TO EVALUATE EFFECT OF JUJUBA BASED FRUIT LEATHER IN MOTION SICKNESS WITH SPECIAL REFERENCE TO FATIGUE AND HEADACHE.**

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### **Abstract**

Motion sickness is an ancient problem having afflicted humans for thousands of years and it has been associated with transportation, it is an uncomfortable condition caused by exposure to unfamiliar or unnatural motion stimuli. The most dramatic descriptions of motion sickness in the medical literature are those of seasickness. Other common situations which may provoke motion sickness are car, train, air and space travel, merry-go-rounds, swings and amusement park rides, and also static devices with a large moving visual display designed to simulate any of the above-mentioned forms of motion. Motion sickness having a set of symptoms like a general discomfort, eye strain, nausea, vertigo, blurred vision, fatigue and headache etc. In this background a need was felt to validate the efficacy of the jujuba based fruit leather, a product developed by DFRL Mysore, for its anti-motion sickness effect mainly fatigue and headache. The result of pre-clinical study of the product was encouraging; hence clinical trial was taken up.

**Keywords:** Motion sickness, motion stimuli, Rotation chair, Jujuba based fruit leather, fatigue and headache.

### **Introduction:**

Ayurveda, the science of life focuses on prevention and cure of diseases. In this era of modernization and globalization, there has been a rise in

various health issues. New diseases which were previously not known to the mankind have started bothering the mankind. Various infectious diseases were on the rise in the past

but now a day, new lifestyle disorders and other diseases have grabbed the attention of the medical fraternity. One among them is the motion sickness. Though this illness was known to medical fraternity, this has undergone a huge rise in past decade. Contemporary medicine has very little to offer to patient of motion sickness. Symptomatic relief is the one that is being offered.

This has made the patient population and scientific fraternity to look at alternative systems of medicine for relief and cure of MS. In light of this, motion sickness which has not been explained directly in Ayurvedic classics has been chosen. Revalidations of the medicines which have been told to be useful in chardi were chosen and developed product out of those drugs for clinical study. Hence the present study was planned to evaluate whether symptoms of fatigue and headache of motion sickness can be achieved by administration of jujuba based fruit leather.

#### **AIM AND OBJECTIVES:**

To evaluate the formulated jujuba based fruit leather in patient with

fatigue and headache in motion sickness.

#### **Material and methods:**

A minimum of 30 individual fulfilling inclusion criteria approaching the inpatient and outpatient department of Government Ayurveda medical college and hospital Mysore and special camp conducted in and around the Mysore were selected and patients fulfilling the diagnostic criteria respective of age, irrespective sex religion and socioeconomic status were selected. To create motion sickness mechanically, rotation chair was prepared

#### **Inclusion criteria:**

- ✓ Patients of either sex between the age group of 18-60yrs.
- ✓ Patients with symptoms of fatigue and headache in motion sickness.
- ✓ Patients willing to participate in this study.

#### **Exclusion criteria:**

- Patients suffering from other systemic illnesses and on any other medications.
- Pregnancy and lactating women.
- Patients suffering from ocular or vestibular disorders.

- Patients who underwent surgery of gastro-intestinal system.

**Protocol:**

The study protocol was approved by the ethical committee of GAMC Mysore. Participants gave written informed consent prior to inclusion, and completed disclosure of the study purpose was offered to all participants before the study procedure.

**Rotation Procedure<sup>1</sup>:** Instructions to the participant before starting the rotation procedure.

1. The rotation procedure consists of 5 min of rotation at a constant speed of 120 degrees/sec (20 rounds per min)
2. The participant hear a beep every 10 sec. During rotations, the participant was instructed to move his/her head up and down when he/she heard the beep tone.
3. Participants should not vomit during the procedure and can skip head movements or tell the experimenter to stop the rotation in time. However, the runs can be interrupted immediately, or the entire procedure can be stopped if necessary.
4. After rotation procedure the participants were asked to rate the SSQ<sup>2</sup>.

**Assessment criteria:**

Objective parameters were assessed before and after intervention by simulator sickness questionnaire (SSQ)

**Grouping of patient:**

The study design will be randomised clinical trial with a pre and post test assessment. Patients were categorized into a single group.

**INTERVENTION:**

Patients will be assigned into a group of 30 subjects.

Group-: jujube based fruit leather 10gms

Source: DFRL Mysore

Dosage: 10gms

Mode of administration: orally

Duration of administration: 1day

**Statistical analysis:**

- 1) Descriptive statistics.
- 2) Chi square test
- 3) Contingency table analysis and
- 4) Repeated measures ANOVA by using window SPSS soft ware

**Observation and Results:**

**a) Fatigue**

In present study below maintained statistical result before treatment 10(33.30%) individual didn't not experienced fatigue, 15(50.00%) complained slight 5(16.70%)

complained moderate fatigue. After treatment 15(50.00), individual didn't experienced fatigue, 14(48.70%) complaint slight, 1( 3.30%) complained moderate fatigue .

headache, 9(30.00%) complained slight, 11( 36.70%) moderate complaining headache, 5(16.70%) sever headache. After treatment 12( 40.00%) didn't developed the headache,13(43.30%) slight headache,5(16.70%) moderate.

**b) Headache**

In case of headache 5(16.70%) individual didn't experienced

**Table no. 1 : Showing percentage change in "Fatigue" before and after treatment.**

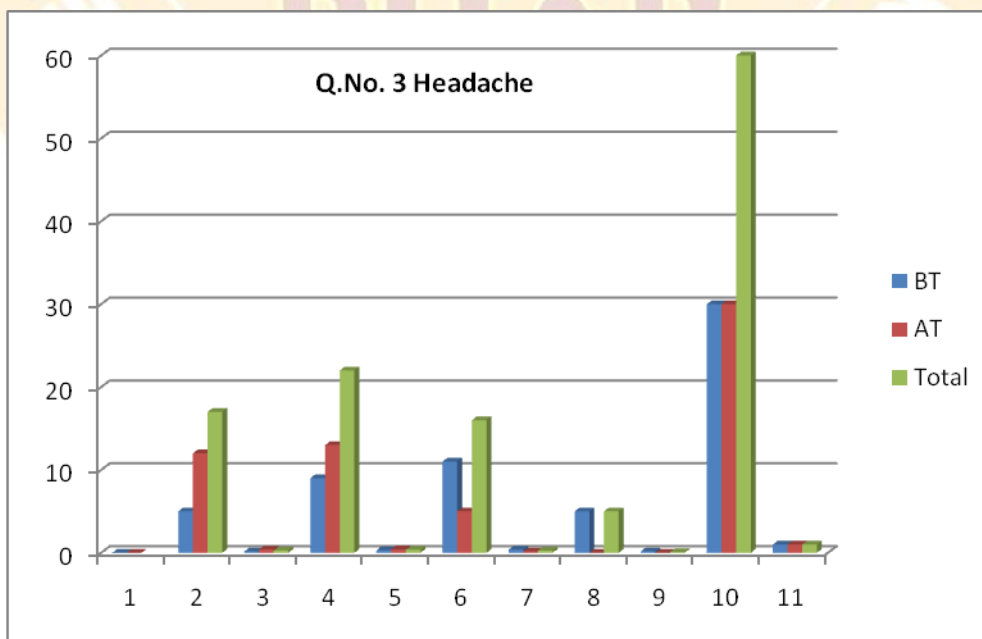
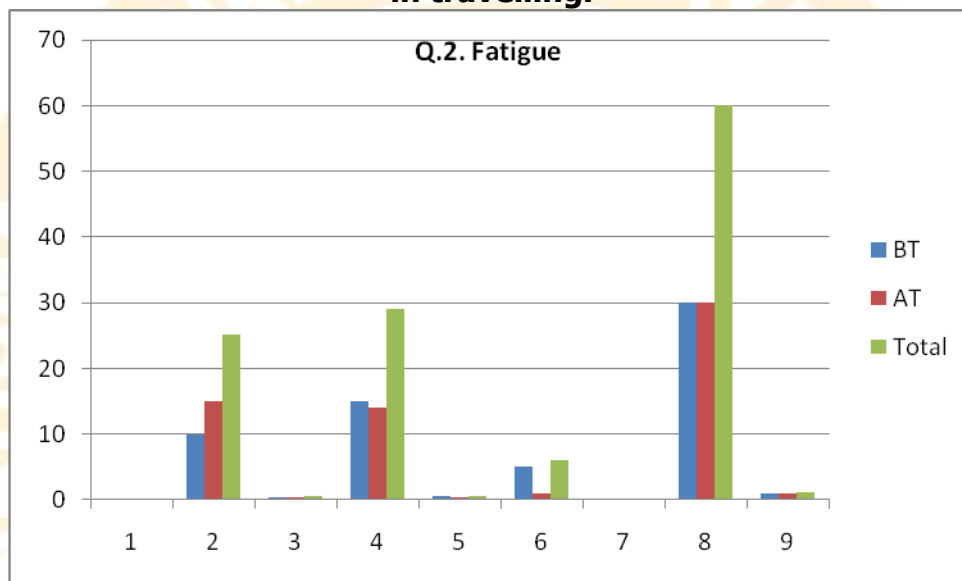
		Q.2 Fatigue		Total
		BT	AT	
<b>Nil</b>	Count	10	15	25
	% within time	33.30%	50.00%	41.70%
<b>Slight</b>	Count	15	14	29
	% within time	50.00%	46.70%	48.30%
<b>Moderate</b>	Count	5	1	6
	% within time	16.70%	3.30%	10.00%
<b>Total</b>	Count	30	30	60
	% within time	100.00%	100.00%	100.00%

**Table no. 2 : Showing percentage change in "Headache" before and after treatment.**

		Q.3 Headache		Total
		BT	AT	
<b>Nil</b>	Count	5	12	17
	% within time	16.70%	40.00%	28.30%
<b>Slight</b>	Count	9	13	22
	% within time	30.00%	43.30%	36.70%
<b>Moderate</b>	Count	11	5	16

	% within time	36.70%	16.70%	26.70%
<b>Severe</b>	Count	5	0	5
	% within time	16.70%	0.00%	8.30%
<b>Total</b>	Count	30	30	60
	% within time	100.00%	100.00%	100.00%

**Graph no .1 showing the classical symptoms of motion sickness observed in travelling.**





**Table No.3 Showing the " P- values" of sixteen symptoms of the Assessment Scale "SSQ"**

Symptoms	P values
Fatigue	0.157
Headache	0.013

From the above result it states that, jujube based fruit leather is showed spastically not significant results in controlling, fatigue (0.157) and headache (0.013)

## Discussion

### Discussion on motion sickness

Motion sickness is a common problem faced by most people while travelling by bus, car, train, airplane and boats. It starts with restlessness and later leads to dizziness, fatigue and headache, nausea and vomiting. It is otherwise known as travel sickness or kinetosis in scientific terms. Motion sickness can be seen in perfectly healthy individuals. There is no age restriction for this condition. But as per a research, it is proven that women are more prone to motion sickness than men. Children usually till the age of two years do not get motion sickness. It may develop as they gradually grow. Almost 33% people are prone to motion sickness even in very mild circumstances and 66% people are vulnerable in severe

circumstances like travelling by car or a boat.<sup>3</sup>

Motion sickness is not an illness, but rather a natural autonomic response to an unfamiliar or specific stimulus. The bodily responses to motion sickness are highly individual and contextually dependent, making them difficult to predict. The initial autonomic responses are similar to the ones demonstrated when under stress. When under the influence of motion sickness, motivation and ability to perform tasks or duties are limited. However, little is known about how specific cognitive functions are affected. Furthermore, standard mitigation strategies involve medications that induce fatigue or strategies that require cognitive capabilities. Both of them may result in reduced capability to perform assigned

tasks or duties. Hence, there is a need for alternative mitigation strategies.

At first, the science of motion sickness may not seem appealing, but rather evoke bad memories and traumas associated with nausea and vomiting. However, when realizing that motion sickness is so much more than just these moments of emesis – that it is the result of a complex set of events that originates from a normal bodily reaction to something that, by the brain, is interpreted as a conflict, toxin, risk or threat – it becomes interesting. Despite its name, motion sickness is just a normal response to an unfamiliar stimulus, initiated long before actually sense anything with the perception.

Motion sickness is the uncomfortable dizziness, fatigue, headache nausea, and vomiting that people experience when their sense of balance and equilibrium is disturbed by constant motion. Riding in a car, aboard a ship or boat, or riding on a swing all cause stimulation of the vestibular system and visual stimulation that often leads to discomfort.

### **Discussion on materials and methods**

#### 1) Drug extraction method

Due to non-availability of jujuba fruits in all seasons, the method of lyophilization for extraction has been selected. The fresh fruit of jujuba were collected, ground and subjected to lyophilization to preserve the powder of jujuba.

2) Place of work - The Experimental work was carried out in “Defence Food Research Laboratory”- Mysuru. This laboratory is reputed central government institute and had all the materials required for the study. There was an on-going project related to motion sickness ,which is incorporated for the benefit of army people to ease the motion sickness and more ever which would give more inputs to this study

#### **Rotation chair:**

The time of administration of drugs was decided based on previous studies conducted on similar study design i.e. as thirty minutes before rotation procedure.

There are many models to induce motion sickness for ex. exposure to Virtual environment, travelling in ghat section, Rotation chair etc. Among them, Rotation chair was used to

induce or simulate the symptoms of MS in the study subjects. As it was reliable, feasible, cost effective, and which was easy method to evaluate the symptoms of motion sickness by appropriate objective parameters rather depending on the subjective parameters.

Procedure of simulation -The rotation procedure consists of 5 min of rotation at a constant speed of 120 degrees/sec (20 rounds per min), which contains adjustable regulator according to weight of the study subjects. During rotations, the participant hears a beep every 10 sec. The participants were instructed to move head up and down when beep tone was heard. They were instructed to do so to induce the "Coriolis effect" (the experience of an illusionary tumbling movement that leads to symptoms of nausea).

#### **DISCUSSION ON METHODS:**

##### **Discussion on Inclusion Criteria:**

Patients suffering fatigue and headache from motion sickness of age group 18 to 60 years were selected despite the fact that MS is more prevalent in younger age group, a broader age group was selected, so as

to facilitate easy recruitment of subjects to the study.

##### **Discussion on Exclusion Criteria:**

Patients with any other systemic disorders and patients who underwent surgery of gastro-intestinal system were excluded to avoid the interference in the action of the drug and also to avoid complications.

The presence of these conditions could possibly trigger or aggravate MS like symptoms fatigue and headache when simulated by the rotation and also would aggravate the symptoms.

##### **Discussion on Diagnostic Criteria:**

Most widely used and standardized diagnostic criteria i.e. ICD-10 which is accepted worldwide was incorporated in the study for the recruitment of subjects. The symptoms fatigue and headache. The subjects with symptoms were selected for the study.

##### **Discussion on Assessment Criteria:**

For clinical assessment: Objective parameters were taken using Simulator Sickness Questionnaire. The SSQ is widely used to describe and assess simulator sickness. Simulator sickness is similar to motion sickness



in that it generally results in feelings of fatigue, headache, nausea, dizziness, vertigo, and sweating (among other symptoms). The questionnaire asks participants to score 16 symptoms on a four point scale (0-3).

There are many questionnaires available to assess motion sickness for ex. MSSQ

And many different ways to assess simulator sickness (e.g., Gianaros, Muth, Mordkoff, Levine, & Stern, 2001); however the most popular is the Simulator Sickness Questionnaire (SSQ). The SSQ was published 20 years ago (Kennedy, Lane, Berbaum, & Lilienthal, 1993) and has since been cited over 800 times (Google Scholar, 2012).

It is used as a reliable assessment measure for the effect of treatment.

With the permission and supply of the questionnaire from Kennedy, R.S., Lane, N.E., Berbaum, K.S., & Lilienthal, M.G. (1993). Simulator Sickness Questionnaire: An enhanced method for quantifying simulator sickness. [International Journal of Aviation Psychology, 3(3),] was taken.

In the present study, the severity of motion sickness was assessed using the

Simulator Sickness Questionnaire. The SSQ was designed to assess the severity of a variety of symptoms that are often associated with motion sickness, such as fatigue, eyestrain, vertigo and nausea. It was not designed to indicate, on a yes/no basis, whether any individual was or was not motion sick (R. S. Kennedy, personal communication, September 2007). The SSQ was administered at the pre and post test of the present study which was suitable for this study set up.

The Questionnaire consisted of 16 parameters on two domains namely,

A. Nausea items

B. Oculomotor items

**Nausea items-** In the questionnaire parameter general discomfort, salivation increasing, sweating, nausea, dizziness with eye open and eye closed, vertigo, stomach awareness and burping comes under nausea items because they are triggered by the vagal nerve and it produced above symptoms

**Oculomotor items-** In the questionnaire parameter fatigue, headache, eye strain, difficulty focusing, fullness of head and blurred

vision, these items are considered under oculomotor items because of disturbance between audio-visual sensory

With these two domains, effect of drugs on motion sickness was clinically evaluated.

**Ethics:** All ethical norms were strictly abided in the trial and sufficient amount of time was given to the subject to accept or reject for participation in the trial.

#### **Discussion on drug**

useful anti-motion sickness drugs in contemporary science like Meclizine 50 mg, Cinnarizine, promethazine, Cyclizine 50 mg etc are used. Many anti-emetic drugs targeting these receptors are currently in use but they also cause undesirable side effects such as excessive sedation, Hypotension, Dry mouth, dysphoria, hallucination and extra pyramidal signs.

Present study was to carry the efficacy of jujube based fruit leather on motion sickness. Vomiting /chardi is the distressing symptoms of MS. Treating motion sickness focuses on easing fatigue, headache. Ayurveda has many drugs that have charadri hara property. Badar (Zizyphus jujube) is

one among charadriharana gana dravya of Charaka Samhita. It is indicated in Kaiyadeva Nighantu for chardi. Dose was decided as per the reference in classical text. Hence used in the similar fashion i.e. jujube based fruit leather -10 gm was administered orally. There were no adverse effects noticed hence jujube based fruit is safe for administration. Fruit leather is a dehydrated fruit-based confectionary dietary product which is often eaten as snack or dessert, which is also called as fruit bar or a fruit slab. Development of fruit leather is termed as post-harvest technology. Consuming fruit leather is an economic and convenient value-added substitute for natural fruits as a source of various nutritional elements. Fruit pulp-based leathers are nutritious and organoleptically acceptable. They contain substantial quantities of dietary fibers, carbohydrates, minerals, vitamins, and antioxidants.

Zizyphus jujube Lam. (Rhamnaceae) is commonly known as "Ber (Jujube)". Fruits of jujube are edible, sweet-sour to taste and widely grown all over India. In India, jujube fruits are being consumed as fresh (raw, juice), dried





statistically not significant of fatigue and headache. Jujube based fruit leather helps for other set symptoms of motion sickness for further study increase in their time duration of susceptibility in rotation chair before and after treatment. Also some slight the significant reduction in symptoms because the nutrient values present in jujube based leather. There were no adverse effects noticed hence Jujuba based fruit leather is safe for administration.

### **References**

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**Source of Support: NIL**

**Conflict of Interest : None declared**