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RCT OF EMAMI BLENDED EDIBLE VEGETABLE OIL ON MAINTAINING / IMPROVING IMMUNITY ALONG WITH CARDIO-VASCULAR HEALTH, DIABETES, GASTRIC HEALTH AND BONE HEALTH

Cardiology

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ABSTRACT

Due to the modern food habits and lifestyle that include consumption of junk, unhealthy food, lack of exercise, improper sleep, we are getting more prone to 'metabolic syndrome' or 'lifestyle disorders'. Metabolic syndrome is a clustering of abdominal obesity, hypertriglyceridemia, low HDL cholesterol, hyperglycaemia, hypertension, low bone density, weak immunity, digestive impairment etc. Nowadays, this syndrome is prevailing in all age groups and not only restricted to middle ages. Studies in urban India found about one-third of Indians suffer from metabolic syndrome.
Emami Agrotech Ltd., Kolkata formulated the Emami Blended Edible Vegetable Oil – EBEVO 3 (blend of 2 oils with vitamins A,C,D,E and omega 3 according to DRD) i.e., Emami Healthy & Tasty Immunity Booster which is meant to maintain/ improve the metabolic syndrome.
Therefore a multi-centric, double blind, randomized and controlled clinical trial was undertaken at 8 distinct sites in Kolkata under 2 investigators. A volunteer pool of 100 healthy participants were recruited based on inclusion criteria of the trial. Healthy as well as participants who were prone to or diagnosed as suffering from any of the five health disorders(Immunity, Cardio vascular diseases/hypertension, Diabetes, GI problems &Acidity and Bone health).
Results: In order to assess the efficacy of the products specific pathological parameters were set for diagnosis before and after the treatment. The results are also indicative of Group A (EBEVO 3) oil showing positive changes, maintenance of normal range before and after consumption in systemic disease parameters such as Immunity status, Cardio-vascular health, Diabetes, Gastric health and Bone Health.

KEYWORDS

Metabolic syndrome, Immunity, Diabetes, Cardio-vascular health, Gastric health.

INTRODUCTION:

The outcome of sedentary and overloaded lifestyle resulted into various health hazards like weak immunity, diabetes, stress, elevation in cholesterol level, hypertension, low bone density, Cardiovascular complications etc. This is only due to our modern lifestyle and changed food habit. So, need of regular vitamins intake is always essential and everywhere observed for which the best daily administrative route is food items specially edible oil (with added vitamins). So, scientists of R & D EmamiAgrotech Ltd. formulated (Emami Healthy & Tasty Immunity Booster oil) with additional vitamins like A,C,D & E in scientifically balanced dosage based on DRD. To evaluate the efficacy of value addition, this clinical research on healthy volunteers (with minor maintainable disorders) was conducted at 8 sites under 2 investigators from 15.5.2019 to 31.10.2020 emphasizing more on the maintenance of arising metabolic disorders.

A. Base Edible Oils

I. RICE BRAN OIL

During the polishing process of the rice, a unique vegetable oil rich in anti-oxidants is extracted from the outer layer of rice, what is known as Rice bran oil (RBO). The studies around the globe have confirmed the cholesterol lowering properties due to presence of unique nutraceutical in this oil known as oryzanol & tocotrienols. Despite its similarities to other common vegetable oils, rice bran oil offers several unique properties that make it very interesting as specialty oil in niche markets. It has a very appealing nut-likeflavour and once extracted is very stable with good fry-life. But perhaps its most notable feature is its high level of components with nutraceutical value such as γ-oryzanol and tocotrienols[1].

II. REFINED SOYBEAN OIL

Soybean oil is one of the most common oils across the world and has suitable nutritional value due tohigh content of linoleic acid, linolenic acid, and antioxidant compounds. Since this oil has high amount of linolenic acid, its oxidative stability, especially at high temperatures, is low and thus is not suitable for frying. The seeds contain up to 48% protein and up to 22% oil, which is widely consumed as cooking oil. The storage soy proteins consist of a mixture of proteins (R-, α-, and γ-conclycinins, glycinin, and other globulins)ranging in molecular weight from about 140000 to 300000 Da anddiffering in physico-chemical and other properties.

The seeds also contain bioactive proteins including α-amylase, cytochrome c, lectin, lipoxygenase, urease, the K unit z inhibitor of trypsin(KTI), and the Bowman-Birkinhibitor of chymotrypsin and trypsin, as well as secondary metabolites including isoflavones, saponins, phyticacid, flatus-producing oligosaccharides, and goitrogens[2]. The soybean is a dicotyledon seed (two cotyledons) held together by the hull. On removal of the hull, the cotyledons separate and the germ is dislodged. The commercial soybean contains about 8% hull, 90% cotyledons, and 2% hypocotyl.

Advantages

- Cholesterol-lowering effects
- Role of Isoflavones
- Soybean Bowman-Birk Inhibitor as an anticarcinogen
- Soybean Lipids and Micronutrient Profiles
- Nutritional Profile: Soybean oil is low in saturated fat, contains no trans-fat, and is high in poly- and mono-unsaturated fats. It's also the principal source of omega-3 fatty acids and the primary commercial source of vitamin E in the U.S.diet.

B. Vitamins

I. Vitamin A: Vitamin A (Vit. A) is a micronutrient that is crucial for maintaining vision, promoting growth and development, and protecting epithelium and mucus integrity in the body. Vit. A is known as an anti- inflammatory vitamin because of its critical role in enhancing immune function. Vit. A is involved in the development of the immune system and plays regulatory roles in cellular immune responses and humoral immune processes. Vit. A has demonstrated a therapeutic effect in the treatment of various infectious diseases.

II. Vitamin C: Ascorbic acid is also known as vitamin C, was initially identified as the factor preventing the scurvy disease, and became very popular for its antioxidant properties. Vitamin C is important in all stressful conditions that are linked to inflammatory processes and involve immunity. It has been known for decades that the persistence of an inflammatory stimulus is responsible for the onset of many diseases.

III. Vitamin D: Vitamin D may come from three potential sources: nutritional sources, UVB-dependent endogenous production and supplements. The classical, hormonal actions of vitamin D are related to mineral metabolism and skeletal health. Vit. D enhances intestinal calcium and phosphate absorption, stimulates osteoclast differentiation and calcium reabsorption from bone and promotes mineralization of the bone matrix.

IV. Vitamin E: Vitamin E is a fat-soluble antioxidant that can protect the polyunsaturated fatty acids (PUFAs) in the membrane from oxidation, regulate the production of reactive oxygen species (ROS) and reactivenitrogen species (RNS), and modulate signal transduction.

C. Omega 3 fatty acid: Omega-3 fatty acids exerts major alterations on the activation of cells from both the innate and the adaptive immune system, although the mechanisms for such regulation are diverse.

First, as a constitutive part of the cellular membrane, omega-3 fatty acids can regulate cellular membrane properties, such as membrane fluidity or complex assembly in lipid rafts.

Formulation

Nutritional information of Emami Blended Edible Vegetable Oil per 100 gm

NUTRITIONAL INFORMATION PER 100G (Approximate composition)	
Energy	900Kcal
Protein Carbohydrate (including sugar)	0g 0g
Total Fat	100g
Saturated fat	12 to 20g
Mono-unsaturated fat	24 to 32g
Poly-unsaturated fat	48 to 60g
(Out of whichALA-Omega3)	5 to 7 g
Trans fat	0.5 to 1.5g
Cholesterol	0 mg
Oryzanol	250mg
Naturally Occurring Vit - E 30 - 40 mg	
Added Vitamin C*	13.4 -14.4 mg
Added Vitamin A	600 - 990µg
Added Vitamin D	11 -16µg
Added Vitamin E	3400 -3500µg

D. *Vitamin C = 13.4 – 14.4 mg ≈ 350ppm.

Study Objectives

Primary Objectives

- Maintenance of / improvement in immunity.
- Maintenance of / improvement in cardio-vascular health including hypertension and dyslipidemia
- Maintenance of / improvement in blood sugar management.
- Maintenance of / improvement in gastro-intestinal symptoms like, acidity, indigestion, flatulence, abdominal discomfort etc.
- Maintenance of / improvement in bone and joint health.

Secondary Objectives

- Maintaining/improvement on quality of life (QOL)

The acceptability and efficacy parameters under the objectives of five subjective and symptomatic diseases (as stated above) are given below:

- Questionnaire based on quality of life experiences
- History directed physical examinations (including, hand grip test)
- Pathological laboratory investigations (blood parameters; invasive method)
- Bone mineral density scanning (non-invasive method)

Investigational Plan

TRIAL DESIGN

The study was a randomized, multi-centric, double-blind and controlled. The clinical trial protocol, patient information sheets, case record form, synopsis and consent forms were approved by the Ethical Committee of the Independent Research Ethics Society. The study was conducted after receiving the consent from the Ethics Committee (March 15, 2019). The Investigators have strictly followed the Standard Operating Procedures (SOPs) for the study following the Good Clinical Practice (GCP) and adhered to the Declaration of Helsinki. He/she thoroughly examined the study participants in his/her specific center(s).

Participants either have to be suffering from one or more than one complications out of five selective diseases/complications and therefore, their specific examination parameters were further categorized under one or more than one sub-group, after selection and randomization of the participants.

Only diet habit or lifestyle modification will be the main consideration. They will continue the schedule cooking edible vegetable oils as prescribed. Investigators will instruct the participants to follow the rules (do's and don'ts) throughout the study period including the product details and feedback information sheet.

After screening a total of 120 volunteers / study participants, 113 volunteers / participants gave written informed consent was included in the study. The participants were randomly enrolled in one of the major groups (Arm- A or Arm- B) by AB: BA rule.

Arm-I	EBEVO 3	Emami Blended Edible Vegetable Oil (Emami Healthy & Tasty Immunity Oil)	56 study participants
Arm-II	EBEVO 4	Himani Best Choice Sunflower Oil	57 study participants

At the commencement of the study, the investigators/ sponsor issued both the test and control oils as per the dosage requirement (30 gm/day or 1 liter per subject per month) of the study participants. Additional test oils are also given at the same quantity to all other family members of the participants.

Investigators instructed the participants to follow the rules (do's and don'ts) throughout the study period including the product details and feedback information sheet. The following assessments were done in the screening visit and also will be done in the coming final visit.

Inclusion Criteria

- Male and female subjects in the age group of 18 years and above.
- Healthy Volunteers/ suffering under any one or more of the signs and symptoms like hypertension, dyslipidaemia, diabetes, GI related symptoms, skin related symptoms and weak in bone health
- Participants willing to give the written informed consent.
- Participants are fit and no need of any hospital administration.
- Willing to cook with the supplied oil.
- Agree to following instruction of do's and don'ts in regular daily lifestyle.
- Subjects/ volunteers/ study participants willing to perform all study related procedures including the use of the study oil, allow the physical and other tests and willing to document symptoms and medication.
- Subjects/ volunteers/ study participants {and /or legally accepted representative (LAR)} willing to give the written informed consent and ability to adhere to dosing and visit schedules and meet study requirements.

Exclusion Criteria

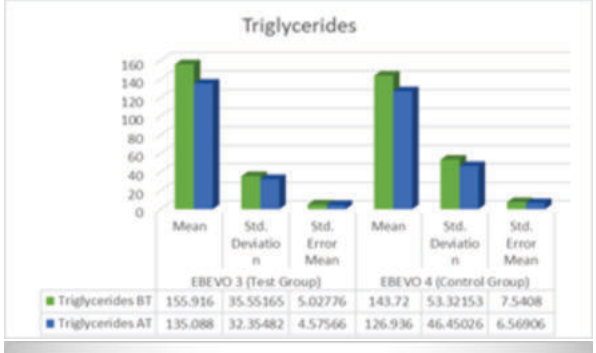
- Volunteers/ study participants unlikely to comply with the protocol or unable to understand the nature, scope and possible consequences of the study.
- Inability to carry out necessary testing for the study.
- Chronic &acute disorders requiring hospital admission
- Known HIV-positive, Hepatitis B or C status.
- Urine pregnancy test positive or pregnant in case of female.
- Suffering from chronic skin disorders.

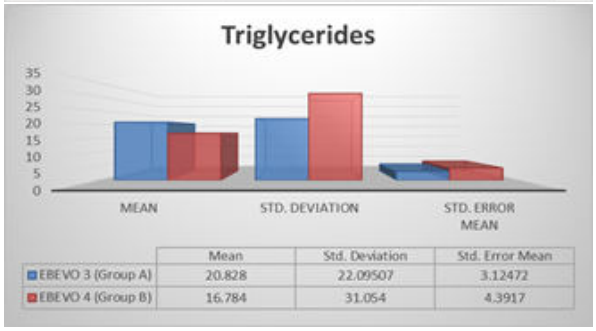
RESULT AND ANALYSIS

OVERALL ANALYSIS

EBEVO 3: N=50

EBEVO 4: N=50





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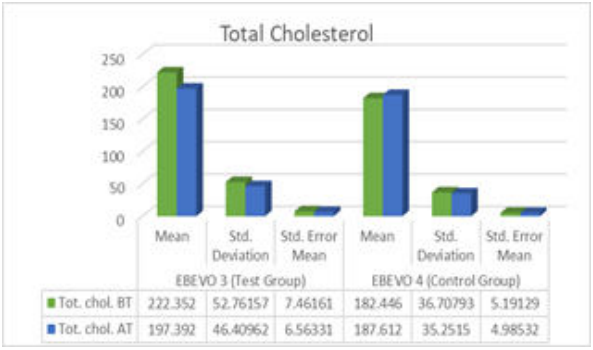

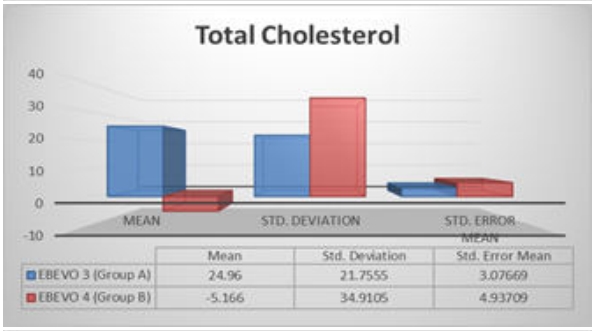

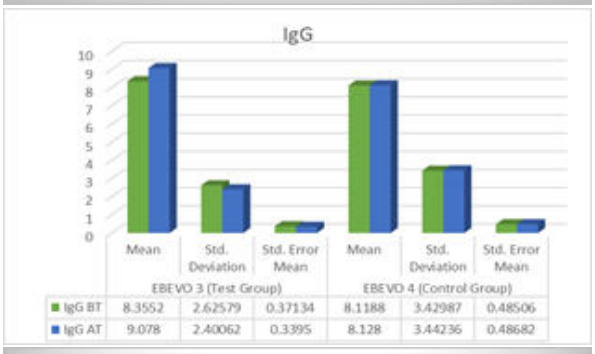

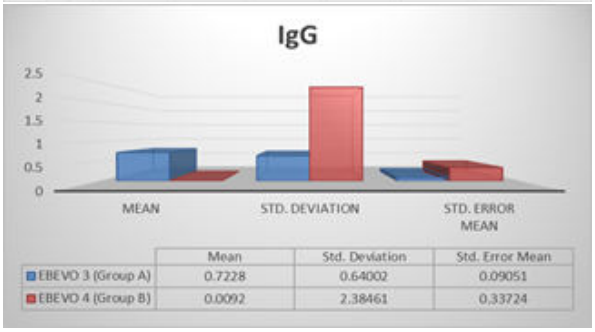

Feedback Survey Analysis
(EBEVO 3:n=50; EBEVO 4:n=50)

Procedure:

- After the completion of the trial i.e., 8 months a survey was carried out in the supervision of Trial coordinator.
- Randomly questions were verified by investigators telephonically. After the compilation of the data, the factors were analyzed percentage wise & compared group wise.
- Video testimonials of volunteers about the efficacy of the oil was recorded.

We found that in comparison to Group B, Group A shows lighter colour of oil before cooking. The colour of EBEVO 3 is lighter than EBEVO 4. From the survey, it was noted that 70% of Group A observed the oil lighter before cooking in comparison to 64% of Group B.

In comparison to Group B, Group A shows lighter colour of oil after cooking. The colour of EBEVO 3 is lighter than EBEVO 4. From the survey, it was noted that 72% of Group A observed the oil lighter after cooking in comparison to 48% of Group B.

In comparison to Group B, Group A shows good aroma of cooked food. The aroma of cooked food with EBEVO 3 oil is better than aroma of cooked food with EBEVO 4 oil. From the survey, it was noted that 80% of Group A found the aroma of the cooked food is good in comparison to 40% of Group B.

In comparison to Group B, Group A shows less smoke while heating.The smoke produced during cooking of EBEVO 3 is less than EBEVO 4 oil. From the survey, it was noted that 18% of Group A observed the oil smoky in comparison to 30% of Group B.

In contrast to Group B, Group A is less sticky. 86% of Group A found EBEVO3 oil non sticky whereas 76% of Group B found EBEVO 4 non-sticky. . It is thus concluded, from the statistical evidence that the group of volunteers used EBEVO 3 oil found it less sticky than EBEVO 4 oil.

Food cooked in EBEVO 3 oil absorbs less oil than EBEVO 4. Therefore, 80% of the total volunteers in Group A found EBEVO 3 less absorptive than 66% of Group B volunteers.

It was found that in comparison to Group B, Group A found the oil more transparent. It is clear that 80% of Group A volunteers marked the oil transparent whereas only 70% of Group B marked EBEVO 4 transparent than the previous oil. So, it is concluded that according to the survey done EBEVO 3 is more transparent than EBEVO 4.

In comparison to Group B, Group A found the oil thinner. From the survey, it is clear that 75% of Group A volunteers marked the oil thin whereas only 56% of Group B marked EBEVO 4 oil thinner than the previous oil. So, it is concluded that according to the survey done the thickness of EBEVO 3oil is less than EBEVO 4 oil.

From the survey, it is observed that the taste of the food is better when cooked in EBEVO3 oil rather than EBEVO 4 oil as 80% of Group A found the food tasty when cooked in EBEVO 3 oil whereas only 60% of Group B found the food tasty using EBEVO 4 oil.

It is observed from the survey that about 80% of Group A volunteers felt light after taking food cooked in EBEVO 3 whereas 24% of Group B volunteers had difficulties digesting the food and felt heavy. Therefore, it is concluded that EBEVO 3 is more light and easily digestible than EBEVO 4 oil.

Easily Digestible

The survey shows that only 4% of Group A faced difficulty in digestion i.e., approximately 68% of Group A claimed the oil to be very effective in digestion whereas only 43% of Group B found EBEVO 4 effective in digestion. Thus, it can be concluded from the survey of feedback form EBEVO 3 is more easily digestible than EBEVO 4 oil.

Hyperacidity

The survey shows that only 60% of Group A didn't have any difficulty of acidity i.e., approximately 66% of Group A claimed the oil to be very effective in digestion whereas only 28% of Group B found EBEVO 4 effective in digestion. Thus, it can be concluded from the survey of feedback form EBEVO 3 is more easily digestible than EBEVO 4 oil.

From the survey, it is clear that about 78% of volunteers in Group A felt a increase in stamina as compared to Group B , where only 48% of Group B volunteers shows increase in stamina. Thus, EBEVO 3 oil has a potential to increase stamina compared to EBEVO 4.

From the survey, it is clear that about 50% of volunteers in Group A shows their cardiovascular health is balanced/improved as compared to Group B , where only 20% of Group B volunteers shows increase in stamina. Thus, EBEVO 3 oil has a potential to balance hypertension/ heart health compared to EBEVO 4 oil.

About 80% of Group A volunteers shown improvement in quality of life whereas 60% of Group B shows the same. So, according to the statistical analysis done on the basis of survey volunteers taking EBEVO 3 experienced an improvement in quality of life than that of EBEVO 4.

It is observed from the survey that the volunteers from Group A suffered from cold & cough less frequently as compared to that of Group B. Thus, we can draw an inference that EBEVO 3 oil can

increase immunity than EBEVO 4.

DISCUSSION

In our study the mean difference of BT and AT shows changes in group EBEVO 3 compared to more changes in group EBEVO 4.

The Independent Samples t Test compares the means of two independent groups in order to determine whether there is statistical evidence that the associated population means are significantly different. The Independent Samples t Test is a parametric test.

Since $p < .05$, we can conclude that the mean difference of the parameters between EBEVO 3 (test group) and EBEVO 4 (control group) is significantly different. The parameters Haemoglobin, Erythrocyte, Platelet count, Neutrophil, ESR, AEC, Total Bilirubin, Alkaline phosphatase, Albumin, Total Cholesterol, HDL, LDL, VLDL, IgG, Urea, Creatinine, Sodium, Potassium, Calcium, Phosphorous and Diastole BP depicts that EBEVO 3 is having better results compare to EBEVO 4.

Although significant difference was not found between EBEVO 3 and EBEVO 4 at the statistical level of significance, changes before and after was observed in the following parameters Leucocyte, FBG, HbA1c, Neutrophil, AEC, Triglycerides, HDL, Total Cholesterol, Systole BP, Left hand grip test and Right hand grip test.

The paired sample t-test, sometimes called the dependent sample t-test, is a statistical procedure used to determine whether the mean difference between two sets of observations is zero. In a paired sample t-test, each subject or entity is measured twice, resulting in pairs of observations. As the p-value is less than 0.05 (i.e., $p < .05$), it can be concluded that there is a statistically significant difference between two variable scores of the parameters Haemoglobin, Erythrocyte, Platelet count, Neutrophil, ESR, AEC, Total Bilirubin, Alkaline phosphatase, Total Cholesterol, HDL, LDL, VLDL, IgG, Creatinine, Sodium, Potassium, Calcium, Phosphorous, Leucocyte, FBG, SGPT, SGOT, Triglycerides and Diastole BP (EBEVO 3).

The paired sample t-test, sometimes called the dependent sample t-test, is a statistical procedure used to determine whether the mean difference between two sets of observations is zero. In a paired sample t-test, each subject or entity is measured twice, resulting in pairs of observations. As the p-value is less than 0.05 (i.e., $p < .05$), it can be concluded that there is a statistically significant difference between two variable scores of the parameters Haemoglobin, Erythrocyte, AEC, Alkaline phosphatase, HDL, VLDL, Sodium, Potassium, FBG, Triglycerides, Diastole BP and Right hand grip test (EBEVO 4).

CONCLUSION:

From the performed trial we can conclude that the oil is quiet effective in maintaining or in some case improving the metabolic syndromes i.e., it has shown significant improvement in immunity, lowering hyperacidity, maintaining the cholesterol level, maintenance of diabetes. Therefore, it can be infered that intake of this edible oil on daily basis can meet the vitamin requirement as well as maintain our immunity, diabetes, cardiovascular health, gastric health and bone health.

REFERENCES

1. Biochemical Constituents and Antinutritional Factors of Soya Bean (Glycinemax) Seeds. Journal of the Science of Food and Agriculture, Vol. 73, No. 1, (January 1997), pp1-9.
2. U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2010. 7th Edition, Washington, DC: U.S. Government Printing Office, December 2010. Available from: http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/PolicyDoc/PolicyDoc.pdf
3. Zhao,Y.; Martin, B.R. & Weaver, C.M.(2005). Calcium Bioavailability of Calcium Carbonate Fortified Soya milk is Equivalent to Cow's Milk in Young Women. The Journal of Nutrition, Vol. 135; No.10, (October 2005), pp. 2379-2382.
4. Soybean and nutrition. Edited by Hany A. El-Shemy. Published by JanezaTrdine 9,51000 Rijeka, Croatia (2011).