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Impact of dietary and herbal supplements on global health of adult volunteers

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ABSTRACT

The safety and efficacy of multivitamin-multimineral-multiherbal (MVMH) supplementation is in regular debate but should be studied in detail before recommendation. The purpose of the study was to evaluate whether MVMH supplementation affects the physical and mental performance of individuals taking these, as well as to ascertain its safety, doing so through blood, kidney and liver profiles.

In this Cross over cohort study, we enrolled 30 healthy volunteers and established their anthropometric, stress, anxiety and depression levels before and after 30 days of the study. Their kidney function test, liver function test and blood profile results were also analysed to determine overall health effects of the supplement and assess its safety. Parametric data was examined via Paired T test, followed by One Way ANOVA, Non-parametric data is presented as percentage and analysed by applying Paired Sample Wilcoxon Signal Rank Test followed by Friedman ANOVA test.

All the volunteers were in good health, had no change in medical state. No serious adverse event was reported during the study and after the completion of study. Treatment with MVMH tablets had shown very significant ($p < 0.01$) increase in the level of globulin, uric acid ($p < 0.05$), hemoglobin, and hematocrit levels ($p < 0.05$), BMI and body weight ($p < 0.05$). There was significant ($p < 0.05$) improvement in symptoms of anxiety, depression and stress.

The daily intake of MVMH supplements in the form of a tablet once per day improved global health of individuals, along with improvement in mental performance without any significant adverse impact on the body. Based on the results, we recommend that MVMH tablets may be taken once per day for 30 days to improve the physical and mental health of individuals.

INTRODUCTION

We are living in a world where health is prioritized for everyone. Because of the increment of pollution and unhealthy life style, there is rise in the diseases such as diabetes, tuberculosis, hypertension, physical deformities, etc. Everyone wants to be healthy, fit and fine, in order to achieve the healthy state, most of the people eat healthy food, exercise and sometimes add dietary supplements in their diet. The primary aim of the nutraceutical products is to target the population having deficiencies of vitamins and minerals that increase the possibilities of malnutrition [1].

Vitamins such as vitamin A, vitamin D, vitamin B complex, etc. represent a wide category of biotic elements that are minor but still important for the growth and functioning of the body. Although good eating habits, which include consuming fruits, vegetables, grains and pulses in the daily diet, can help in taking care of nutrient loss occurring during repository and preparing processes [2], the intake of multivitamin and multimineral tablets and capsules can help in replacing the loss of minerals and vitamins.

Lack of Multivitamins can cause physical, as well as mental loss [3]. Multivitamin tablets not only help in recovering from physical deficiency, but there are studies that demonstrate that these supplements help in overcoming

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stress, anxiety and depression. During the pandemic, there were huge loss of human life. According to one research study, massive amounts of people faced emotional and psychological shock at this time, even the cases of divorce increased in some countries [4]. People got tired more easily after performing small tasks, and there was the condition of mental exacerbation due to loss of loved ones [5]. This caused conflict at home which exacerbated mental disturbance [6].

Taking supplements such as vitamins, minerals and herbal ingredients has positive effects on people physical and mental health. Indeed, it has already been demonstrated through various studies that herbs such as *withania somnifera* help in boosting brain activity, while Turmeric and Giloy act as immunity boosters [7]. Furthermore, natural herbal ingredients like tulsi, giloy, turmeric, ashwagandha have also been shown to have beneficial effects on the people's health. The same can be said for the intake of minerals such as zinc, iron, calcium etc. Thus, products containing multivitamins, herbal ingredients and minerals have application in maintaining a healthy life style.

In recent years, there has been an amplification of various market claims regarding the intake of multi-vitamin supplements [8]. According to current data, there has been a nearly 23% increase in sales of such products in India, while globally, the sales have increased from \$18.24 billion in 2021, to \$19.98 billion in 2022 [9]. These increases in sales follow a decades long trend that has come about due to people's awareness of the health benefits of taking in dietary supplements worldwide [10]. Accordingly, the percentage of people taking nutraceutical products has also increased. In this case, from 40% to 70% [11] across the globe.

The primary objective of the study was to develop tablets of multivitamins, minerals, and herbal composition as per the guidelines of FSSAI and Good manufacturing practice (GMP). The secondary objective was to evaluate safety and efficacy of the developed tablets in healthy volunteers for 30 days treatment.

METHODS

Study participants

There was a total of 40 participants who agreed to take part in this study. Of these, 30 were eligible due to criterion of inclusion of healthy volunteers who are office workers, above 18 years of age, having no serious disease and who are interested enough to participate [12]. The study began June 1, 2022 and ended 31, August, 2022. At the start, blood samples of 5 mL was withdrawn from each individual to record baseline of liver function and kidney function, as well as blood profile. Questionnaires on stress, anxiety and depression was also circulated amongst the participants so as to obtain knowledge of their mental status (Figure 1).

Intervention

After supplementation of one multivitamin tablet of 1000 mg orally per day for 30 days, a set of tests were conducted on day 30. The blood profile assessment, kidney function and liver function tests were re-performed to determine differences. Change in mental functioning was reassessed using

the same questionnaires. The blood tests were conducted in NABL certified laboratories.

Anthropometric parameters

Anthropometric measurement was taken before and after 30 days of daily oral intake of the MVMH tablet. It included chest circumference, arm circumference, waist circumference, height, weight and BMI. The chest, waist and arm circumference were measured by tape measure, while height was determined with the help of stadiometer without shoes, and weight was assessed with the help of a digital weighing scale. The BMI was then calculated.

Biochemical parameters

Kidney and liver profile i.e., 11 parameters in liver profile test, 6 in kidney profile test and 17 parameters in blood profile test were estimated from the taken 5 mL blood samples. These parameters helps in knowing the potential effect of MVMH tablets intake on kidney and liver profile parameters (creatinine, serum calcium levels, etc.).

Hematological profiling

34 blood parameters were established through the same samples. These include: Hemogram, TLC (total leucocytes), neutrophils, lymphocytes, Eosinophils, Monocytes, Basophils, Red blood cells count, Hematocrit, MCV, MCH, MCHC, RDW-CV, RDW-SD, Platelets, MPV and ESR.

Mental health study

The mental health of study participants was carried out using standard questionnaires that were filled out before and after the study period. The questionnaires included one with questions seeking demographic information, and a second – the World Health Organization quality of life standard questionnaire that sought information on mental status [13]. This questionnaire was divided in three parts. The first was assessment of stress; the second, for anxiety; and the third, depression. The score of this questionnaire was converted into 0 to 4 – the higher the score, the higher the levels of stress, anxiety and depression.

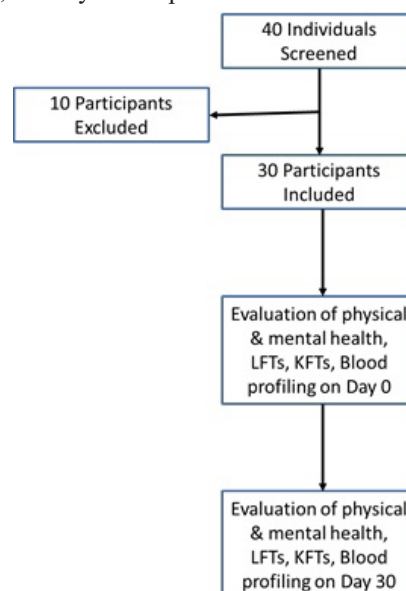


Figure 1. Selection of participants

Composition of tablets

Each 1000 mg tablet was composed of the following vitamins; Vitamin A, Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B5, Vitamin B6, Biotin, Folic acid, Vitamin B12, Vitamin C, Vitamin D3 and Vitamin E. The mineral component included: Potassium, Magnesium, Manganese, Chromium, Copper, Selenium, Zinc, Molybdenum, Iodine, Iron and Calcium. The multiple amino acid components incorporated are: Choline Bitartrate, Inositol and L-Tryptophan. Herbal extracts found within the manufactured tables consisted of: Ashwagandha Extract, Valerian Extract, Safed Muesli Extract, Mucuna Pruriens Extract, Ginseng Extract, Tribulus Terrestris Extract, Grape Seed Extract, Lutein and Lycopene. The proportions and individual chemical formulae are listed in Table 1.

Method of preparation of tablets

The Multivitamin tablets were developed in Pure Source Nutrition Pvt. Ltd. New Delhi under proper guidelines set by the FSSAI (food safety and standards Authority of India). The company is fully authorized to develop nutraceutical products as per GMP guidelines.

Validation of tablets

All the ingredients and levels of incorporation are listed in the FSSAI guidelines and approved by FSSAI.

Tablets stability study

Accelerated stability testing was performed for 1 month duration of time. The test was conducted by a Government recognized laboratory. All the ingredients were checked for stability using normal phase HPLC (high performance liquid chromatography), ICP and FD Techniques, respectively. The product was assessed for stability in a gap of 5 days for each ingredient. Description, color, average weight, moisture content, total ash, energy, carbohydrates content, protein content and fat content were determined per 100 grams of weight.

Bioethics

The study was carried out upon the approval by University Research Ethics Committee of DIT University Dehradun for involving human subjects. This was granted on 12 May 2022 under the protocol no. DITU/UREC/2022/04/7. Participants written informed consent was taken individually after a face-face interview. The participants were first educated about the objective of the study. Information provided by participants and generated during the study remained confidential. All participants were free to withdraw from the study at any point without giving any reason. All individuals' informed consent forms were collected and filed for confidential reasons in secure storage.

Statistical analysis

The data were collected on hardcopies and entered in excel sheet for further analysis. All numerical results are expressed as Mean \pm SD. The data were analysed by paired T test, followed by One way ANOVA. The qualitative results are expressed in terms of frequency and percentage and

Table 1. Composition of tablets

Ingredients	Unit	Qty/serving
Vitamin A	mcg/tab	600.0
Vitamin B1	mg/tab	1.4
Vitamin B2	mg/tab	1.6
Vitamin B3	mg/tab	18.0
Vitamin B5	mg/tab	5.0
Vitamin B6	mg/tab	2.0
Biotin	mcg/tab	30.0
Folic acid	mcg/tab	200.0
Vitamin B12	mcg/tab	1.0
Vitamin C	mg/tab	40.0
Vitamin D3	mcg/tab	10.0
Vitamin E	mg/tab	10.0
Potassium	mg/tab	90.0
Magnesium	mg/tab	40.0
Manganese	mg/tab	4.0
Chromium	mcg/tab	50.0
Copper	mg/tab	1.7
Selenium	mcg/tab	40.0
Zinc	mg/tab	12.0
Molybdenum	mcg/tab	45.0
Iodine	mcg/tab	100.0
Iron	mg/tab	17.0
Calcium	mg/tab	49.0
Choline Bitartrate	mg/tab	35.0
Inositol	mg/tab	30.0
L-Tryptophan	mg/tab	50.0
Ashwagandha Extract	mg/tab	50.0
Valerian Extract	mg/tab	25.0
Safed Muesli Extract	mg/tab	40.0
Mucuna Pruriens Extract	mg/tab	25.0
Ginseng Extract	mg/tab	50.0
Tribulus Terrestris Extract	mg/tab	40.0
Grape Seed Extract	mg/tab	50.0
Lutein	mg/tab	10.0
Lycopene	mg/tab	20.0
Excipients	mg/tab	Q.S.

were analyzed by Paired Sample Wilcoxon Signal Rank Test, followed by Friedman ANOVA test. The level of significance are represented as significant $p < 0.05$ (*), very significant $p < 0.01$ (**) and highly significant $p < 0.001$ (***)

RESULTS

Evaluation of tablets

Tablets were evaluated for physical and chemical composition. All component of the tablets were within the permissible limit as mentioned by FSSAI. The analysis of tablets was done in detail and the strength of an individual component is given in Table 2.

Table 2. Analysis of MVMH tablets

Chemical Parameters				
Appearance	Brick red colour film Coated	Zinc (Zinc sulphate)	mg/tab	12
Shape	elongated tablet	Molybdenum (Sodium molybdate)	mcg/tab	45.02
Odour	Characteristic	Manganese (Manganese sulphate)	mg/tab	40
Color	Brick red	Copper (Cupric gluconate)	mg/cap	1.71
Average Weight	mg/tab	1149.5 Iodine (Potassium Iodide)	mcg/tab	100
Disintegration Time	minutes	18-19 Chromium (Chromium picoinate)	mcg/tab	50.03
Moisture	g/100 g	5.76 Selenium (Sodium selenate)	mcg/tab	40
Total Ash	g/100 g	0.37 Calcium (Calcium carbonate)	mg/tab	49.5
Energy	kcal/100 g	377.98 Choline bitartrate	mg/tab	35.22
Carbohydrate	g/100 g	82.42 Inositol	mg/tab	30.02
Protein	g/100 g	10.95 L-Tryptophan	mg/tab	50.1
Fat	g/100 g	0.5 Lutein	mg/tab	10.08
Vitamin C (L-Ascorbic Acid)	mg/tab	40.04 Lycopene	mg/tab	20.08
Vitamin B6 (Pyridoxine)	mg/tab	2.02 Vitamin B1 (Thiamine mononitrate)	mg/tab	1.41
Vitamin E (D-Alpha tocopherol)	mg/tab	10 Vitamin B2 (Riboflavin)	mg/tab	1.66
Vitamin B12 (Cyanocobalamin)	mg/tab	1.03 Vitamin B3 (Nicotinamide)	mcg/tab	18
Vitamin A (Retinyl acetate)	mcg/tab	600.02 Vitamin B5 (D-pantothenate, calcium)	mcg/tab	504
Vitamin D3 (Cholecalciferol)	mcg/tab	10.01 Potassium (Potassium chloride)	mg/tab	90
Biotin	mcg/tab	30.26 Folic acid	mcg/tab	200
Iron (Ferrous Fumarate)	mg/tab	17.01 Magnesium (Magnesium sulphate)	mg/tab	40
Herbs				
Ashwagandha (<i>Withania somnifera</i>)	mg/tab	49.85 Kaunch beej (<i>Mucuna Pruriens</i>)	mg/tab	25
Valerian (<i>Valeriana officinalis</i>)	mg/tab	24.8 Ginseng (<i>Panax ginseng</i>) Extract	mg/tab	50
Safed Musli (<i>Chlorophytum</i>)	mg/tab	39.78 Gokhru (<i>Trihulas Terrestris</i>) Extract	mg/tab	39.82
		Grape Seed (<i>Vitis vinifera</i>) Extract	mg/tab	49.89

Stability study

Stability study of tablets were carried out in seven randomly selected MVMH tablets as mentioned above. There was no significant change observed in the tablets (Table 3).

Anthropometric parameters

As shown in Figure 2 all anthropometric factors remained unaltered except the body weight and BMI. The average body weight changed significantly ($p < 0.05$) – from 72.8 kg to 73.43 kgs. Accordingly, the BMI of participants also changed significantly ($p < 0.05$) from 26 to 26.17.

Biochemical parameters

Liver Function Test

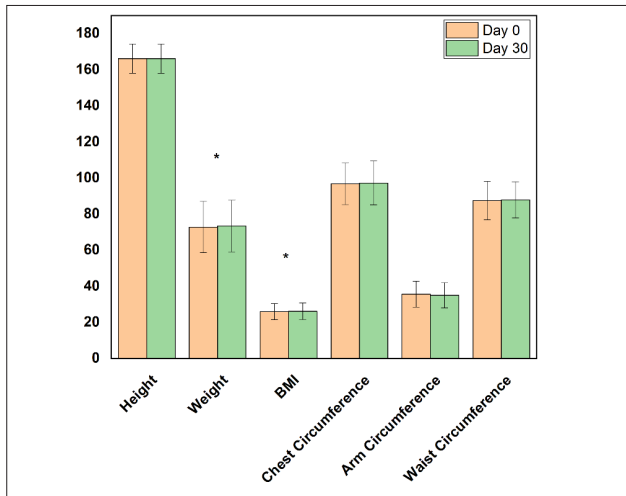
The result of 30 days of MVMH tablets intake revealed a very significant ($p < 0.01$) increase in the level of globulin. A highly significant ($p < 0.001$) increase in albumin to globulin ratio was also seen after 30 days of intervention. Other parameters remained unchanged (Figure 3).

Table 3. Stability study of tablets

Description	Brick red film coated elongate tablets	
Odour	Characteristics	
Colour	Brick red	
Average weight	mg/tab	1150
Moisture	g/100 g	5.75±0.019
Total ash	g/100 g	0.39
Energy	kcal/100 g	378.07±0.11
Carbohydrates	g/100 g	82.3±0.023
Protein	g/100 g	11.04±0.03
Fat	g/100 g	0.52±0.007
Vitamin C	mg/tab	40.06±0.03
Vitamin B1	mg/tab	1.46±0.04
Vitamin B2	mg/tab	1.65±0.02
Vitamin B3	mg/tab	18.11±0.04
Vitamin B5	mg/tab	5.08±0.04
Vitamin B6	mg/tab	2.04±0.02
Vitamin E	mg/tab	10.17±0.07
Vitamin B12	mcg/tab	1.04±0.03
Vitamin D2	mcg/tab	600.02±0.01
Vitamin D3	mcg/tab	10.01±0.007
Potassium	mg/tab	91.35±1.03
Folic acid	mg/tab	200.03±0.01
Biotin	mcg/tab	30.23±0.1
Iron	mg/tab	17.1±0.06
Magnesium	mg/tab	40.93±0.067
Zinc	mg/tab	12.07±0.05
Molybdenum	mcg/tab	45.11±0.08
Manganese	mg/tab	4.12±0.07
Copper	mg/tab	1.77±0.05
Chromium	mcg/tab	50.12±0.08
Selenium	mcg/tab	40.13±0.13
Calcium	mg/tab	51.36±1.03
Choline bitartrate	mg/tab	35.23±0.1
Inositol	mg/tab	30.09±0.05
L-Tryptophan	mg/tab	50.21±0.3
Lutem	mg/tab	10.13±0.07
Lycopene	mg/tab	20.33±0.34
Ashwagandha Extract	mg/tab	50.13±0.07
Valerian Extract	mg/tab	25.11±0.06
Safed Musli	mg/tab	40.14±0.07
Kaunch beej Extract	mg/tab	25.33±0.15
Ginseng Extract	mg/tab	50.19±0.1
Gokhru Extract	mg/tab	40.13±0.06
Grape Seed Extract	mg/tab	50.16±0.07
Iodine	mcg/tab	101.36±0.94

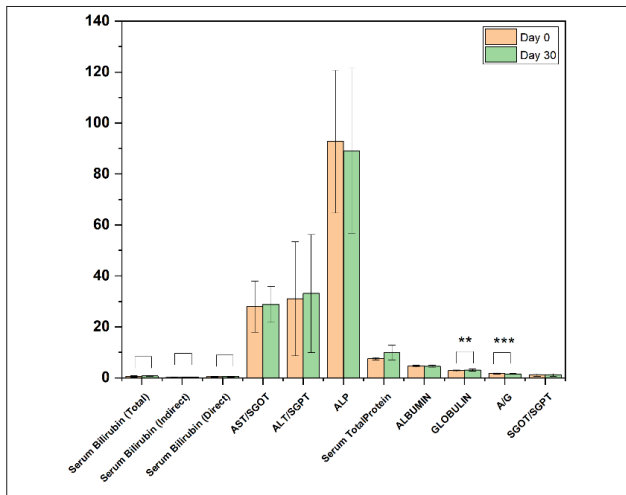
Renal Function Test

The outcome of kidney function testing is shown in Figure 4. Accordingly, the mean value of uric acid significantly ($p < 0.05$) increased from 5.09 to 5.42, while other kidney function parameters remained unchanged.



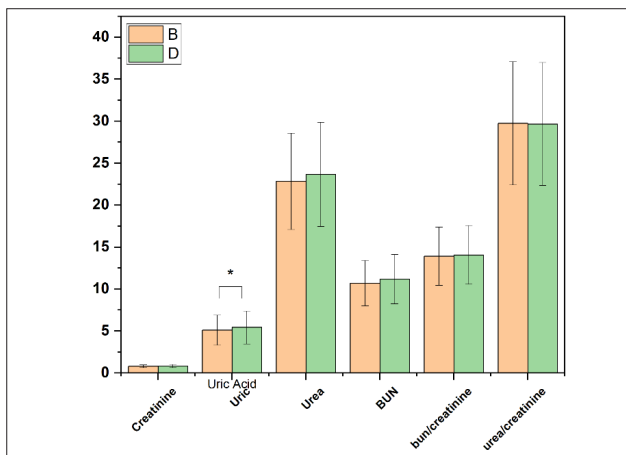
Results are presented as Mean ± SD. The data were analyzed by paired T test followed by One way ANOVA. The level of significance are represented as significant $p < 0.05$ (*)

Figure 2. Comparative analysis of anthropometric parameters before and after the MVMH supplementation



Results are presented as Mean ± SD. The data were analyzed by paired T test followed by One way ANOVA. The level of significance are represented as significant $p < 0.05$ (*), very significant $p < 0.01$ (**) and highly significant $p < 0.001$ (***)

Figure 3. Comparative analysis of liver function parameters before and after the MVMH supplementation

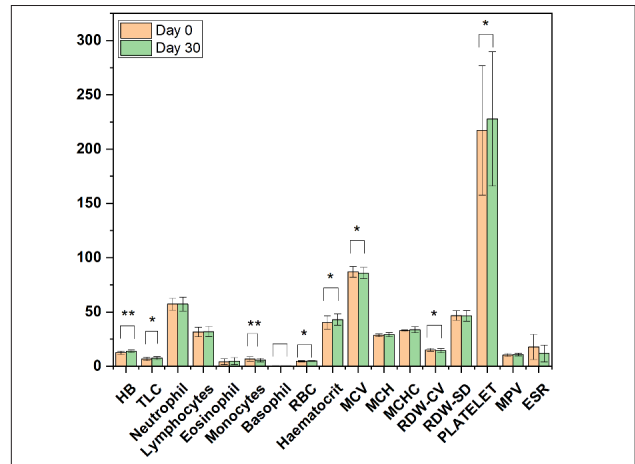


Results are presented as Mean ± SD. The data were analyzed by paired T test followed by One way ANOVA. The level of significance are represented as significant $p < 0.05$ (*), very significant $p < 0.01$ (**) and highly significant $p < 0.001$ (***)

Figure 4. Comparative analysis of kidney function parameters before and after the MVMH supplementation

Hematological profiling

The hematological Profile is revealed in Figure 5. Herein, the mean HB value increased very significantly ($p < 0.01$) from 12.5 to 13.8, whereas monocyte levels are reduced from 6.75 to 5.74. There was also a significant ($p < 0.05$) increase in RBC count, TLC count, Eosinophil, platelet count and level of hematocrit. However, a significant ($p < 0.05$) decrease in RDW-CV was noted.



Results are presented as Mean ± SD. The data were analyzed by paired T test followed by One way ANOVA. The level of significance are represented as significant $p < 0.05$ (*), very significant $p < 0.01$ (**) and highly significant $p < 0.001$ (***)

Figure 5. Comparative analysis of blood profile of samples before and after the MVMH supplementation

Mental health

Stress

Treatment with the nutritional supplement significantly ($p < 0.05$) reduced stress levels, especially the perception of difficulty in completing assigned tasks (Table 4).

Table 4. Effect of 30 days treatment with mvmh tables on stress

Questions	Assessment of Level of Stress										
	Day 0 (%)					Day 30 (%)					P Value
	Never	Almost	Sometime	Fairly Often	Very Often	Never	Almost	Sometime	Fairly Often	Very Often	
Conflict at home	26.7	50	23.3	-	-	73.3	23.3	-	3.3	-	-
Felt nervous and stress	20	50	23.3	6.7	-	63.3	23.3	6.7	3.3	3.3	0.05
Upset	46.7	23.3	13.3	16.7	-	73.3	20	3.3	3.3	-	-
Felt confident	46.7	35.7	13.3	3.3	-	70	-	13.3	10	6.7	-
Control irritation	43.3	53.3	-	3.3	-	-	73.3	16.7	3.3	6.7	-
Unable to control the important things	43.3	43.3	6.7	3.3	3.3	10	60	30	-	-	-
Felt that things were going your way	60	33.3	-	3.3	3.3	-	-	43.3	23.3	33.3	-
Could not cope with all the things	56.7	20	23.3	-	-	20	10	53.3	16.7	-	-
Felt on top of things	40	30	23.3	6.7	-	-	-	16.7	20	63.3	-
Outside of control	70	-	13.3	16.7	-	26.7	6.7	60	3.3	3.3	-
Could not overcome difficulties	63.3	20	13.3	3.3	-	13.3	3.3	60	23.3	-	-

Anxiety

The current nutritional supplement significantly ($p < 0.05$) improved upon feelings of being worried, of experiencing unnecessary worry, of feeling relaxed and resting appropriately, and not becoming easily annoyed or irritated (Table 5).

Table 5. Effect of 30 days treatment with mvmh tables on anxiety

Assessment of Level of Anxiety											
Questions	Day 0 (%)					Day 30 (%)					P Value
	Never	Almost	Sometime	Fairly Often	Very Often	Never	Almost	Sometime	Fairly Often	Very Often	
Feeling nervous, anxious or on edge	26.7	50	23.3	-	-	56.7	20	23.3	-	-	0.01
Unable to stop or control worrying	20	50	23.3	6.7	-	40	30	23.3	6.7	-	0.05
Worrying too much	46.7	23.3	13.3	16.7	-	70	-	13.3	16.7	-	0.05
Trouble relaxing	46.7	36.7	13.3	3.3	-	63.3	20	13.3	3.3	-	-
Restless	43.3	53.3	-	3.3	-	73.3	23.3	-	3.3	-	0.01
Easily annoyed or irritable	43.3	43.3	6.7	3.3	3.3	63.3	23.3	6.7	3.3	3.3	0.05
Feeling afraid	60	33.3	-	3.3	3.3	73.3	20	3.3	3.3	-	-

Depression

With respect to depression, 30 days treatment with MVMH tablets improved significantly ($p < 0.05$) interest in ‘doing things’, in feeling good and in experiencing uninterrupted sleep. Other parameters were insignificantly affected by this intervention (Table 6).

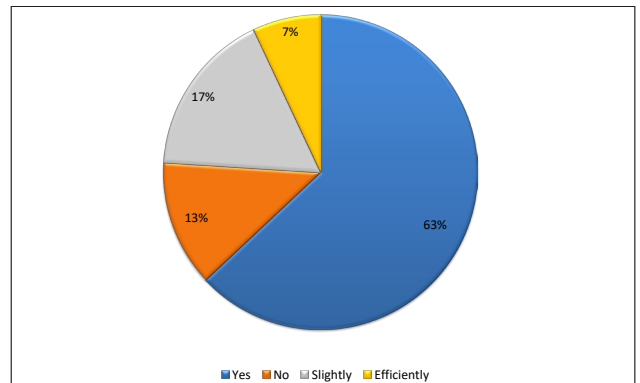
Table 6. Effect of 30 days treatment with mvmh tables on depression

Assessment of Level of Depression											
Questions	Day 0 (%)					Day 30 (%)					P Value
	Not at all	Several days	>1/2 the days	Nearly Every Day	Very Often	Not at all	Several days	>1/2 the days	Nearly Every Day	Very Often	
Little interest or pleasure	40	36.7	6.7	13.3	3.3	60	16.7	6.7	13.3	3.3	0.05
Feeling down, depressed, or hopeless	50	46.7	3.3	-	-	90	6.7	3.3	-	-	0.05
Trouble falling or staying asleep	56.7	26.7	6.7	10	-	80	3.3	6.7	10	-	0.05
Feeling tired	33.3	46.7	10	10	-	43.3	36.7	10	10	-	-
Poor appetite or overeating	56.7	26.7	10	6.7	-	63.3	20	10	6.7	-	-
Feeling bad about self	86.7	10	3.3	-	-	90	6.7	3.3	-	-	-
Trouble concentrating	63.3	23.3	6.7	6.7	-	63.3	23.3	6.7	6.7	-	-
Moving or speaking slowly	70	16.7	6.7	6.7	-	73.3	13.3	6.7	6.7	-	-
Being so fidgety or restless	76.7	23.3	-	-	-	80	20	-	-	-	-
Thoughts of death or suicidal or hurting self	100	-	-	-	-	100	-	-	-	-	-

Need of nutritional supplement

After the completion of 30 days, the study participants were asked to provide their feedback on the effectiveness of the developed MVMH tablets. About 63% of all participants

agreed to the fact that the nutritional supplement helped in improving upon feelings of anxiety, depression, dizziness, fatigue and weakness, while 17% and 7% of all participants (respectively) were of the opinion that it slightly and more or less improved upon these symptoms. In contrast, 13% of the participants held the opinion that there was no improvement (Figure 6).



Results are expressed as percentage

Figure 6. Outcome of MVMH supplementation helped in improving anxiety, depression, dizzy, fatigue and weakness

DISCUSSION

The objective of this study was to investigate the safety and efficacy of the developed MVMH tablets. The outcome of the study shows that there was positive change in the parameters of anthropometric, mental assessment and blood reports. We, thus, successfully achieved the objective of present cohort study. The daily consumption of the developed MVMH tablets enhanced physiological and psychological parameters, and the test subjects felt more energetic and relaxed following one month of tablet intake. The same result can also be seen in a study by Mark A. Levy *et al.* wherein a multivitamin tablet was administered for 4 weeks [14] In previous study, it was noticed that administration of multivitamin tablets improves overall health of elderly patients [15].

There are a plethora of studies on multivitamins supplements. Some are in favour of them, as there are conditions when such supplements help in boosting the energy level and have positive effect on the metabolism of the body, like the mean value of the Haemoglobin content [16].

In this multivitamin study, herbal ingredients such as ashwagandha extract, valerian extract, safed musli, kaunch beej extract, ginseng extract and gokhru extract were added to enhance brain activities [17]. Some related studies have revealed positive effect of their intake. For example, in one Randomized Double-Blind, Placebo-Controlled study involving 64 subjects with chronic stress, Ashwagandha extract was found to safely and effectively enhance resistance to stress and thereby improved quality of life [18]. In another study, an investigation was conducted to study the stress relieving and pharmacological actions of withania Somnifera on 60 adults for 60 days. The result demonstrated that ashwagandha supplement brought about reduction in the HAM-A (Hamilton Anxiety Rating Scale, Depression, Anxiety and stress Scale-21 (DASS-21) [19].

Valerian is a medicinally important herbal product used since ancient times for treating migraine, fatigue, anxiety, depression, headaches and stomach cramps [20]. In one randomized, double-blind crossover clinical trial involving 39 patients with anxiety and depression, valerian was given for one month. The researchers found that valerian significantly improved the symptoms of anxiety and depression. In addition, it helped in overcoming sleep disorders [21].

Another important herb, i.e. safed musli (*Chlorophytum borivilianum*) is used traditionally in Ayurveda, Unani and Homeopathy, and has been found to increase physical performance [22]. Moreover, *Mucuna pruriens*, which is known for its therapeutic properties, was deemed to be beneficial in restoring the monoaminergic neurotransmitter levels in the substantia nigra and was noted to have much better neuroprotective effect in comparison with levodopa [23].

Another important constituent of the developed multivitamin tablet is *Panax Ginseng*. There is much research available on ginseng with regard to its beneficial effects. For instance, in a study regarding ginseng's effect upon psychomotor performance in healthy volunteers, in a double-blind placebo controlled clinical study, it was seen that the effect of this product was positive as there was significant improvement in the state of mind [24]. *Tribulus terrestris* (gokhru) is also a well known medicinal plant used for its therapeutic response. It can be found in herbal medicines as an operational cure for hypertension [25]. In turn, grape seed extract is known to display anti-oxidant properties. In a study involving 36 participants, in a 12 week intervention of blood pressure and metabolic indices with hypertension, the use of grape seed extract declined the risk of hypertension in an at-risk people [26].

The results of our study are in line with these studies with respect to the improvements in the physical and mental performance of healthy volunteers due to the presence of these herbal extracts. The test subjects' anxiety symptoms were significantly negated (feelings of nervousness, anxiety or on edge, worrying, excessive worrying, restlessness and irritability). The nervousness and stress symptoms of the volunteer and his/her family members was also significantly improved. Furthermore, significant improvement in depression symptoms such as lack of interest or pleasure in doing things, feeling down or hopeless and sleeping disturbances, was evident.

The developed MVMH tablets contain amino acids such as L-Tryptophan and Lycopene. These amino acids play a crucial role in body. Tryptophan, apart from balancing the body's nitrogen level, also helps in generating serotonin, a brain chemical neurotransmitter that regulates mood, appetite and sleep [27]. The other amino acid, Lycopene, helps in maintaining bone density and in reducing osteoporosis [28].

Minerals such as calcium, molybdenum, zinc, iodine, selenium, etc. are present in the developed multivitamin. These minerals in an available form help in performing the important functions of the human body [29]. There is much published research on these minerals. For example, zinc is known to be necessary for the proper growth and development of the body [30], and a deficiency of calcium results in osteoporosis [31]. Our results substantiate these studies.

In one study, the lack of vitamins and minerals can cause manifestation of fatigue [32]. Other than this they are also important constituents to maintain the balance between certain metabolic activities in human body. A deficiency of vitamin B1, for example, causes emotional disturbance and weakness and pain in the limbs, while vitamin C deficiency brings about scurvy and iron scarcity produces anemia and much more [33]. The outcome of our study demonstrates that micro and macro nutrient deficiency can be overcome by taking adequate amount of nutrients.

The MVMH tablets developed in our study contains multivitamins, multiminerals, aminoacids and multiple herbal extracts that generally fill the deficiencies of certain multivitamins, minerals, amino acids and herbal extracts recognized as necessary nutritional supplements. The very significant ($p < 0.01$) increase in the level of globulin at the end of the study period in the test population indicates that the supplement could also help in building immunity to fatigue and to common diseases [34]. Increased globulin content in the blood of the test population at the end of the experiment indicates the improvement in protein profile of the volunteers leading to significant increase in uric acid ($p < 0.05$) [35]. The significant ($p < 0.05$) improvement in hemoglobin and hematocrit levels that was indicated could be due to improvement in serum globulin levels, as well as supplementation of necessary vitamins, minerals and other co-factors [36]. In anthropometric analysis there was a significant ($p < 0.05$) improvement in BMI, along with body weight. While healthy volunteers in whom the study was carried out felt energetic physically and mentally [37], for confirmation, we recommend to conduct the study at a larger scale, in a multicentric manner and with the inclusion of a more diverse group of population.

CONCLUSION

In conclusion, this study indicates that the developed MVMH tablet helped in improving the mental, physical and clinical function of the test population. In general, this 4-week intervention supports the role of dietary supplements in improving mental and physical health. The liver and kidney function tests, along with blood profile demonstrates that oral intake of MVMH tablets daily for four weeks had no negative effects on the functioning of these vital organs. This developed multivitamin tablet can, therefore, be a boon to the global population.

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DECLARATIONS

Nil.

ETHICAL APPROVAL

Present study was approved by University Research Ethics Committee of DIT University, Dehradun. Informed consent form was taken from all volunteers for participation and publication of outcome of the study.




COMPETING INTERESTS

Nil.

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