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Evaluating the role of *Majoon Falasfa* (Herbal Formulation) in health promotion of elderly: A randomized single-blind placebo controlled study

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ABSTRACT

The present study was conducted to evaluate the role of *Majoon Falasfa* in health promotion of elderly. A randomized single-blind placebo controlled trial was carried out on 30 patients at National Institute of Unani Medicine Bangalore. After obtaining ethical clearance, 30 eligible patients were randomly assigned into test and control groups. Test group was administered with 10 gm of *Majoon Falasfa* orally in the morning and same dose in the evening for two months while control group was given placebo for the same period of time as that of test drug. Written informed consent was sought from every subject before inclusion in the study. Present study was completed within a period of one year. Response was measured by the assessment of Haemoglobin%, Physical activity score, Appetite score, Weight, Dementia score and Grip strength score. Patients were called for follow up on every 15th day. The results were statistically analyzed by applying Student's 't' test, two tailed dependent for intra group comparison and two tailed independent for intergroup comparison. Test group showed strongly significant increase in Weight ($p<0.001$), Appetite score ($p<0.001$), Grip strength score ($p<0.001$) and Dementia score ($p<0.001$). The study revealed that test drug appeared to be promising in health promotion of elderly and exhibited significant effects in improvement of weight, grip strength, appetite, memory and haemoglobin content hence can be safely recommended as a prophylactic measure in old age to counter the effects of ageing.

Keywords: Unani Medicine, Ageing, Elderly, Health Promotion, *Majoon Falasfa*.

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INTRODUCTION

Ageing is a natural, irreversible and inevitable biological phenomenon.[1] It has been defined as progressive, generalized impairment of functions leading to loss of adaptive response to stress and growing risk of age related diseases, resulting in progressive increase in age specific mortality. The overall effect of these alterations is an increase in the probability of dying, which is evident from the rise in age specific death rates in the population.[2]. Ageing of population is affected due to downward trends in fertility and mortality. In India the population of older people has risen from 4.9% in 1901 to 5.5% in 1951, 6.5% in 1991, and 7.7% in 2001 and will be 12% in 2025. As per 2011 census, percentage of Indians above the age of 60 years is 8.3% (estimated 99.87 million).[3] Senior citizens face a lot of health problems due to ageing process. This ageing process is the result of entropy driven decay, mutations and oxidative stress resulting in generalized impairment of functions, loss of adaptive response to stress, immunosenesence and increasing the risk of age related diseases such as, decrease power, vision, memory, locomotion or immobility, exertional dyspnoea, depression, gastrointestinal distress, loss of appetite, changes in the skin, cardiovascular diseases, respiratory diseases, weight loss and musculoskeletal diseases.[4]

It is uncertain as to why we age. Despite being a universal phenomenon, the exact mechanism or sequence of events are not yet definitively known. Frequently described biochemical markers of ageing include increase in chromosome structural abnormalities, increase in DNA cross-linking, decrease in DNA methylation, loss of DNA telomeric sequences, decline in gene expression, deterioration of mitochondrial structure, increase in post-translational changes in protein structure such as cross linking, glycation, deamidation and oxidation and intra cellular accumulation of metabolic products.[2,5] The growth in scientific, medical and gerontological knowledge and advances in the study of older adults has led to the postulation of various theories of ageing. These include Biological theories (Feature theory, defect theory), Psychological theories (Maslow's Hierarchy of Needs, Erikson's stages of development), Moral/Spiritual theories (Kohlberg's stages of development, Tornstam's theory of Gerotranscendence), Sociological theories (Disengagement theory, Active theory, Continuity theory), Structural damage theories (Wear and tear theory, Waste accumulation theory, Faulty reconstruction theory, Immuno-suppression theory, Error and repair theory, Molecular cross-linkage theory, Mitochondrial damage theory, Free radical theory of ageing) and Entropic theories of ageing.[6,7,8]

According to Unani concept, ageing is the result of *tahleele ratoobate ghareezia* (innate body moisture from which we have been created) by *hararate ghareezia* (normal body heat) and inadequate compensation of *tahleel* (dissolution) by *Quwwate hadima* (power of digestion) that maintain balance or homeostasis. Due to increased *tahleel ratoobate ghareezia* (innate moisture), *hararate ghareezia* (normal body heat) weakens because *ratoobate ghareezia* provide matter for *hararate ghareezia*. *Quwwate hadima* (power of digestion) also get weakened due to weakness in *hararate ghareezia* (normal body heat), ultimately resulting in decreased formation of *akhlat* (humors) and *ratoobat* (moistness), and decreased availability of the substitute of tahleel. Decrease in *hararate ghareezia* (normal body heat) changes the *miza*j (temperament) relatively to *barid* (cold); gradual increase with age in *baroodat (*coldness) results in decline of *quwa* (faculties) thereby *afaal* (functions) of the body. As all *quwa* (faculties) requires *hararat* (heat) for performing *afaal* (function). Depravity of humours or dryness continues neutralizing the *ratoobat* (moisture) of the body until the form ceases to have a capacity for life.[9] According to classical Unani literature the age after 60 years is called as *Sinne Shaikhookhat.* In this age *Mizaj* (temperament) is *Barid Yabis* (cold and dry-extremely), quantity of the *Rutoobate Ghareeziya* (normal body moisture) is deficient and lesser than the quantity required for the preservation of *Hararate Ghareeziya* (normal body heat). There is also dominance of *Rutoobate Ghareeba*. In this period, there is an insidious decline in organ functions. [10,11,12]

With the continuing growth of elderly populations in modern societies, it has become a matter of increasing urgency to look for ways to maintain and improve the functional abilities of ageing people, to help them cope independently in the community and ultimately, to raise the quality of their lives. A number of single and compound drugs like *Amla (Emblica officinalis), Zanjabeel (Zingiber officinale), Asgand (Withenia somnifera), Garlic (Allium sativa), Zafraan (crocus sativa), Kalonji (Nigella sativa), Tiryaq wabai, Majoon Lana, Majoon Falasfa* etc. have been described in Unani literature for the preservation and promotion of health of elderly persons. Some of the drugs studied in recent years demonstrate promising effect. *Majoon Falasfa is one of the most reputed poly pharmaceutical preparations of Unani System of Medicine given particularly in old age to counter the effects of ageing.* It is an electuary containing Maweez munaqa *(Vitis vinefera),* Zanjabeel *(Zingiber officinale),* Filfil Siyah *(Piper nigrum),* Filfil Daraz *(Piper longum),* Darchini *(Cinnamommum zeylanicum),* Amla *(Emblica officinalis),* Post-e-Balela *(Terminalia belerica),* Sheetraj Hindi *(Plumbago zeylanicum),* Zarawand *(Aristolochia indica),* Salab Misri *(Orchis latifolia),* Maghz-e-Narjeel *(Cocus nucifera),* Babuna *(Matricaria chamomillia),* Maghz-e-Chilghoza *(Pinus gerardiana)* and Sugar.[13] According to Unani classical

literature *Majoon Falasfa* has been described as general tonic, cardiac tonic, liver tonic, nervine tonic, *anti-arthritic, aphrodisiac,* carminative as well as good appetizer. [13] *It is being particularly used for enchancing memory, in dementia* and for these reasons it is known as Maadat-ul-Hayaat i.e, elixir of life in old age.[13, 14] Keeping in view the above facts *'Majoon Falasfa' was selected for study to validate its role* as it is acclaimed for the beneficial effects in the prevention of age associated diseases by Unani physicians.

MATERIALS AND METHODS

A randomised single blind, placebo controlled study was carried out at NIUM hospital over a period of one year from May 2013-April 2014.The study was approved by the institutional ethical committee with IEC No. NIUM/IEC/2O11-12/OO1/TST /O1. After ethical clearance patients were questioned and screened for inclusion and exclusion criteria. Detailed information about the study was explained to the participants and written informed consent was taken from all the eligible participants before starting the treatment schedule. Subjects of either gender, ≥ 65 years of age, with history of weight loss, loss of appetite, slow walking/gait speed and low mental score were included in present study. Subjects below 65 years of age, with Diabetes, Hypertension, Chronic Obstructive Pulmonary Disease (COPD), Cardiac or renal disease or with other chronic disease like cancer & AIDS were excluded during enrolment.

In this study, all the patients attending geriatric OPD of the hospital were screened. Patients were selected on the basis of inclusion and exclusion criteria from OPD of National Institute of Unani Medicine Hospital. Selected subjects were randomly allocated into test group and control group by using Lottery method. Written informed consent was obtained from the study subjects before enrolment in the study. A total of 34 patients with routine geriatric problems were selected. Four patients drop out during present study. Test group was administered with 10 gm of *Majoon Falasfa* orally in the morning and same dose in the evening for two months. While control group was given placebo for the same period of time as that of test drug. Patients were particularly advised to take their medicines timely and regularly. Before starting the treatment, detailed information about the patient including signs and symptoms were recorded in the case record form.

In order to assess the appetizer effect of our test formulation Council of Nutrition appetite questionnaire (CNAQ), developed by the council for nutritional strategies in long term care in institutional and community dwelling adults, has been used in this study. It is an 8 item questionnaire with 5 options under each item (question). According to CNAQ, possible scores

range from 8 (worst) to 40 (best). In our study patients were assessed for appetite score on every fortnightly from the baseline upto two months to monitor the improvement in their appetite level. Scores were recorded on case record form and put for statistical analysis at the end of the study.

Grip strength was assessed by using hand dynamometer**.** Patients were instructed to squeeze the dynamometer with maximum isometric effort, which was maintained for 5 seconds.

Reading of the dynamometer was recorded at each follow up upto two months from the baseline of the trial. The scores obtained were put for statistical analysis using appropriate test at the end of the study.

For the assessment of Dementia, a scoring system was done by using Revised Hasegawa's Dementia Scale (HDS-R). It is a short mental status test which is most often needed in the screening of mental impairment in elderly persons and in determining the severity of impairment. HDS-R is an arbitrary scale consisting of 9 simple questions with a maximum score of 30. According to Hasegawa *et al*, sensitivity and specificity were achieved by regarding a score of 20 or less as suggestive of dementia. The dementia score was determined at every follow up to monitor the effect of the test drug and compared statistically using appropriate tests. Physical activity was assessed by using Katz Index of Independence in Activities of Daily Living. Katz Index includes six activities. The score varies from 0 to 6. 0 score is considered as low (patient highly dependent) where as 6 is considered as high (patient highly independent). Patients were assessed for haemoglobin% and weight every fortnightly. Results were recorded on case report form and put for statistical analysis at the end of the study. For safety evaluation of the drug, LFT, RFT and blood glucose were carried out at baseline and at the end of the treatment.

Statistical Methods

Descriptive and inferential statistical analysis was carried out in the present study. Results on continuous measurements were presented by Mean ± SD (Min-Max) and results on categorical measurements were presented in Number (%). Significance was assessed at 5 % level of significance. Student's't' test, two tailed dependent for intragroup comparison, two tailed independent for intergroup comparison was applied.

Significant figures:

+ Suggestive significance (P value: $0.05 < P < 0.10$);* moderately significant (P value: $0.01 < P \leq 0.05$); ** strongly significant (P value: $P \leq 0.001$) were used for the connotation of the significant differences.

Statistical software

The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate tables**.**

RESULTS AND DISCUSSION

In present study maximum number of subjects, 86.7% (26) were in the age group of 65-70 years, 10% (3) in 71-75 years and 3.3 % (1) in 75-80 years (Table 1). Our results are in accordance with the results of the study published by Lena A *et al.* [15] Our study population comprised predominantly of males 70% (21) while remaining 30% (9) were females (Table 1). In several studies, higher prevalence of geriatric problems has been documented in women.[15,16,17] Contrary to the reported prevalence higher percentage of the male patients was observed in the present study. The reason may be smaller sample size and preponderance of male patients visiting NIUM Hospital. In addition, the study sample was taken from the hospital, so it cannot be considered as the representative of general population from which data are given in reference studies. Majority of study subjects 76.7% (23) were non-vegetarian (mixed diet) and 23.3% (7) were vegetarian (Table 1). Our results are in conformity with the scientific report published by WHO. According to the report, many of the diseases suffered by elderly people are the result of dietary factors. Dietary fat seems to be associated with malignancy of the colon, pancreas and prostate. Atherogenic risk factors such as high blood pressure, dyslipemia and glucose intolerance, all of which are considerably affected by dietary factors, plays an important role in the pathogenesis of coronary heart disease. Degenerative diseases such as cerebrovascular and cardiovascular disease, diabetes, osteoporosis and cancer, which are among the most common diseases affecting older persons, are all diet-affected. On the other hand, old age problems are low in vegetarians because food of plant origin contains phytochemicals like carotenoids, isothiocyanates, isoflavones, ellagic acid, glucarates, curcumins, phenolic acids, phthalides, saponins, phytosterols, sulfide compounds, terpenoids and tocotienols. These compounds alter metabolic pathway and hormonal actions, stimulated the immune system and have anti-oxidant activity.[18,19]

In our study maximum subjects 50% (15) were Muslims, 46.7% (14) Hindus and 3.3% (1) Christians (Table 1). Our results are in accordance with the study by Singh L *et al* and Alam M**.** According to their study, Muslims and SCs reported poor self-rated health than other reference groups. Muslims and SCs in general, and women in particular, are at a relatively disadvantageous position in terms of education and economic status in the Indian social strata compared with others.[20,21] In present study population 46.7% (14) subjects belonged to the lower

middle class (III), 26.7% (8) to upper lower class (IV), 20% (6) upper middle (II) and 6.7% (2) from lower class (V) (Table 1). Our study is in accordance with Canada's Health Promotion Survey. According to this survey, "those in the upper-middle income group are far more likely to report excellent or very good self-rated health than those in the poor or very poor income categories. Those in the very poor income group are more than five times as likely to report fair or poor health." In addition, 40% of adults 65 and over in the very poor income group report activity limitations, compared to only 11 % of those in the upper-middle income group. Furthermore, study done by Robert T. Jensen to "explore the relationship between health and SES for the elderly in Russia" confirmed that low SES leads to worse health, which in turn reduces earning capacity.[22,23]

Table 1: Demographic characteristics of participants included in the study

Demographic data		No. of Patients (n=30)	Percentage (%)
Age group	65-70	26	86.7
	71-75	3	10
	75-80	1	13.3
Gender	Male	21	70
	Female	9	30
Diet	Vegetarian	7	23.3
	Mixed	23	76.7
Marital status	Married	29	96.7
	Unmarried	1	3.3
Religion	Muslim	15	50
	Hindu	14	46.7
	Christian	1	3.3
Socioeconomic status	Upper Middle (II)	6	20
	Lower Middle (III)	14	46.6
	Upper Lower(IV)	8	26.7
	Lower(V)	2	6.7

The Mean ± SD of Appetite score in test group was 24.40±3.17, 24.60±3.07, 25.05±3.12, 25.30±2.92 and 26.10±2.88 on 0 day, 15th day, 30th day, 45th day and 60th day respectively. While in control group, the Mean ± SD was 24.80±2.39, 25.00±2.40, 25.00±2.49, 24.90±2.51 and 25.20±2.70 on 0 day, 15th day, 30th day, 45th day and 60th day respectively (Table 2). The Mean ± SD scores of both test and control groups were compared statistically using Student's 't' test (independent) between group and Student's 't' test (dependent) within group, it was found that the difference between the Mean ± SD scores of test group at 60th day with respect to 0 day test and 0 day control was strongly significant ($p<0.001$). Mean ± SD scores of test group were also significant at 30th day ($p<0.001$), 45th day ($p<0.001$), and 60th day ($p<0.001$) as compared to 0 day test and 0 day control groups. Thus, these results showed that the appetite score increased

at every follow up in test group. Control group also showed moderately significant ($p<0.05$) increase in appetite score at 60th day with respect to 0 day control and 0 day test groups. Improvement in appetite in test group might be due *to Mushtahi* (appetizer), *Muqawi meda* (stomachic) and *Hazim* (digestive) properties of the various constituents of the test formulation which have been documented in Unani literature.[14] Different researches have documented the digestive, stomachic and appetizer properties of Maweez *(Vitis vinefera)*, Filfil siyah *(Piper nigrum)*, Zanjabeel *(Zingiber officinale)*, Amla *(Emblica officinalis)*, Balela *(Terminalia belerica)*, Darchini *(Cinnamommum zeylanicum)* and Sheetraj *(Plumbago zeylanicum)*. Study done by Sahar D *et al* have proved that in elderly lower energy intake was associated with lower subjective health status, loss of appetite and more gastrointestinal problems. According to their study, improvement in appetite improves the nutritional status in elderly. Our results are in conformity with this study. Thus, it can be concluded that improvement in appetite improves the general nutritional status in elderly.[24]

Table 2: Comparative Evaluation of Appetite Score in two groups at different time points

Appetite Score	Group 1	Group 2	P value
0d	24.40±3.17	24.80±2.39	0.728
15d	24.60±3.07	25.00±2.40	0.722
30d	25.05±3.12	25.00±2.49	0.965
45d	25.30±2.92	24.90±2.51	0.715
60d	26.10±2.88	25.20±2.70	0.418
Intra group analysis Difference			
• 0d-15d	+0.20	+0.20	-
• 0d-30d	+0.65	+0.20	-
• 0d-45d	+0.90	+0.10	-
• 0d-60d	+1.70	+0.40	-
P value			
• 0d-15d	0.163	0.168	-
• 0d-30d	0.006**	0.168	-
• 0d-45d	0.001**	0.343	-
• 0d-60d	0.002**	0.037*	-

Test used:

Student's 't' test (unpaired) for intergroup analysis and Student's 't' test (paired) for intra group analysis. T_0 day vs T_{60} day ($p<0.001$), C_0 day vs T_{60} day ($p<0.001$).

Where T_0,T_{60}, indicates test group at 0 day and 60th day, C_0 , C_{60} indicates control group at 0 day and 60th day respectively.

Regarding weight, Mean ± SD in test group was found as 65.89±13.87, 66.76±14.10, 67.29±14.12, 67.47±14.05 and 68.11±13.68 on 0 day, 15th day, 30th day, 45th day and 60th day

respectively while in control group Mean ± SD score was 64.44±14.61, 64.35±13.69, 64.76±15.44, 64.93±15.57 and 65.19±15.14 on 0 day, 15th day, 30th day, 45th day and 60th day respectively. (Table3). When the Mean ± SD scores of both test and control groups were compared statistically it was found that the difference between the Mean ± SD scores of test group at 60th day compared with 0 day test and 0 day control was strongly significant ($p<0.001$). Control group showed statistically insignificant results at 60th day ($p>0.05$) as compared to 0 day test and 0 day control group. Improvement in weight in test group might be due to cumulative effects of various ingredients of the test drug with *Mushatahi* (appetizer), *Hazim* (digestive) and *Musamin Badan* (body building) properties.[14,25] The *Mushtahi* (appetizer), and *Hazim* (digestive) properties of Filfil Siyah *(Piper nigrum)*, Zanjabeel *(Zingiber officinale)*, Amla *(Emblica officinalis)*, Balela (Terminalia belerica), Darchini *(Cinnamommum zeylanicum)*, Sheetraj *(Plumbago zeylanicum)* and Maweez Munaqa *(Vitis vinefera)* improves the digestive functions, resulting in increase in appetite and food intake which in turn results in weight gain. Besides the above mentioned properties, the other ingredients of test drug viz; Salab Misri *(Orchis latifolia)* , Narjeel *(Cocus nucifera)*, Maweez Munaqa *(Vitis vinefera)* and Chalghoza (*Pinus gerardiana*- the main ingredient of the test drug) possess the property of *Mughazi* (nutrient) and *Musamin Badan* (body building), hence increases the nutritional status of the body, resulting in weight gain. In addition to this weight gain may be attributed to the presence of certain ingredients in the formulation having oil or carbohydrate content in their chemical composition. The ingredients are Maweez *(Vitis vinefera)*, Chilgozah *(Pinus gerardiana)* and Narjeel *(Cocus nucifera)*. Our results are in consonance with the study done by Sahar D *et al* according to the study lower energy intake was associated with lower subjective health status, loss of appetite and more gastrointestinal problems. Our test drug improves the appetite and digestive functions hence the nutritional status, which in turn increased the weight in elderly. Weight is directly proportional to BMI; by improving the weight in elderly BMI is improved.[24] Diehr P *et al* used longitudinal cohort data from the United States to determine whether weight categories predict subsequent mortality and morbidity in older adults. They reported that who weigh the least had the highest mortality rates.[26] Further more study done by Janssen I *et al* conducted a prospective cohort in the United States to examine the health risks associated with overweight and obese in adults age 65 and older, concluded that BMI <22 kg/m^2 in elderly have highest morbidity and mortality rates. Thus, it can be concluded that improvement in weight in elderly decreases the morbidity and mortality.[27]

Table 3: Comparative Evaluation of Weight (in kg) in two groups at different time points

Weight(in kg)	Group 1	Group 2	P value
0d	65.89±13.87	64.44±14.61	0.793
15d	66.76±14.10	64.35±13.69	0.659
30d	67.29±14.12	64.76±15.44	0.657
45d	67.47±14.05	64.93±15.57	0.656
60d	68.11±13.68	65.19±15.14	0.599
Intra group analysis Difference			
• 0d-15d	+0.87	-0.09	-
• 0d-30d	+1.40	+0.32	-
• 0d-45d	+1.58	+0.49	-
• 0d-60d	+2.22	+0.75	-
P value			
• 0d-15d	0.004**	0.854	-
• 0d-30d	0.001**	0.667	-
• 0d-45d	<0.001**	0.508	-
• 0d-60d	<0.001**	0.184	-

Test used:

Student's 't' test (unpaired) for intergroup analysis and Student's 't' test (paired) for intra group analysis. T_0 day vs T_{60} day ($p<0.001$), C_0 day vs C_{60} day ($p>0.05$), C_0 day vs T_{60} day ($p<0.001$).

In present study, Mean ± SD of Grip strength score in test group was 26.80±12.68 on 0 day, 28.40±13.74 on15th day, 30.75±13.86 on 30th day, 34.40±13.91 on 45th day and 35.80±13.61 on 60th day respectively while in control group Mean ± SD score was 26.50±12.79 on 0 day, 27.20±11.68 on 15th day, 28.50±12.26 on 30th day, 29.40±12.60 on 45th day and 31.80±12.93 on 60th day respectively (Table 4). This data was compared statistically, it was found that the difference between the Mean ± SD scores of test group at 60th day compared with 0 day test and 0 day control was strongly significant ($p<0.001$). Intra group analysis also showed strongly significant improvement in test group at 30th day ($p<0.001$), 45th day ($p<0.001$) and 60th day ($p<0.001$). This showed that there was significant improvement in grip strength at every follow up. Intragroup comparison also showed moderately significant improvement ($p<0.05$) in control group at 60th day as compared to 0 day test and 0 day control groups. Grip strength improvement in control group may be due to their daily dietary intake as no dietary instructions were given to them. However the improvement was only moderately significant when compared to test group where it was strongly significant ($p<0.001$) as shown above. The improvement in grip strength in test group may be attributed to the fact that the test drug improves the nutritional status, hence the general body strength in elderly. The improvement in nutritional status might be because of *Mushatahi* (appetizer), *Hazim* (digestive), *Mughazi* (nutrient) *and Musamin Badan* (body

building) activities of most of the ingredients of test drug viz; Filfil Siyah *(Piper nigrum),* Zanjabeel *(Zingiber officinale),* Amla *(Emblica officinalis),* Balela *(Terminalia belerica),* Darchini *(Cinnamommum zeylanicum),* Sheetraj *(Plumbago zeylanicum),* Maweez Munaqa *(Vitis vinefera),* Salab Misri *(Orchis latifolia),* Narjeel *(Cocus nucifera),* and Chalghoza (*Pinus gerardiana* which is the main ingredient of the test drug). These results are in confirmatory with the properties of the drugs as indicated by the Unani scholars such as Razi, Ibn sina, Momin Khan, Kabeeuddin, Hussain and Kritikar and Basu etc.[25,28,29,30] According to classical Unani literature *Majoon Falasfa* has been described as *general tonic, cardiac tonic, liver tonic, nervine tonic as well as good appetizer.*[13,25,31,32] *For these reasons Majoon Falasfa was originally called Madaat-ul-Hayaat i.e. Elixir of life* [14,25] *in old age. Thus, it can be said with certainty that Majoon Falasfa improves the general body strength in test group and hence grip strength. Our results are in consonance with several scientific studies.* Smith *et al* found a direct correlation in grip strength and overall body strength in very old. The study revealed that, "grip strength was moderately correlated with overall body strength in the very old and oldest populations.[33] Fry *et al* also found a correlation between grip strength and performance in American Men Junior Weightlifting.[34] According to a 2008 University of Iowa study, a strong, firm handshake signifies confidence and strength, whereas a weak, or "dead-fish" handshake conveys weakness and uncertainty. "Good grip strength could reflect overall muscular strength, and cardiovascular health," Blaber wrote. "That's not to say that a strong grip makes you invincible, but according to many studies, there is a correlation between grip strength and overall health." Many of the research studies correlated grip strength to various other physical variables including nutritional status, rotator cuff weakness, fatigue, and overall physical function**.** [35]

Table 4: Comparative Evaluation of Grip strength Score in two groups at different time points

Grip strength Score	Group 1	Group 2	P value
0d	26.80±12.68	26.50±12.79	0.953
15d	28.40±13.74	27.20±11.68	0.815
30d	30.75±13.86	28.50±12.26	0.667
45d	34.40±13.91	29.40±12.60	0.347
60d	35.80±13.61	31.80±12.93	0.447
Intra group analysis Difference			
• 0d-15d	+1.61	+0.70	-
• 0d-30d	+3.96	+2.00	-
• 0d-45d	+7.61	+2.90	-
• 0d-60d	+9.00	+5.30	-

P value			
• 0d-15d	0.032*	0.560	-
• 0d-30d	0.001**	0.334	-
• 0d-45d	<0.001**	0.162	-
• 0d-60d	<0.001**	0.026*	-

Test used:

Student's 't' test (unpaired) for intergroup analysis and Student's 't' test (paired) for intra group analysis. T_0 day vs T_{60} day ($p<0.001$), C_0 day vs C_{60} day ($p<0.05$), C_0 day vs T_{60} day ($p<0.001$).

In our study Mean ± SD of Dementia score was 19.55±4.36 on 0 day, 19.85±3.92 on 15th day, 20.20±3.81 on 30th day, 20.45±4.08 on 45th day and 21.25±3.85 on 60th day while in control group Mean ± SD score was 21.40±4.58 on 0 day, 21.40±4.58 on 15th day, 21.40±4.58 on 30th day, 21.50±4.35 on 45th day and 21.50±4.67 on 60th day respectively. (Table 5). When this data was compared statistically it was found that the difference between the Mean ± SD scores of test group at 60th day with respect to 0 day test and 0 day control was strongly significant ($p<0.001$) while in control group results were statistically insignificant ($p>0.05$).

Table 5: Comparative Evaluation of Dementia Score in two groups at different time points

Dementia Score	Group 1	Group 2	P value
0d	19.55±4.36	21.40±4.58	0.290
15d	19.85±3.92	21.40±4.58	0.342
30d	20.20±3.81	21.40±4.58	0.453
45d	20.45±4.08	21.50±4.35	0.521
60d	21.25±3.85	21.50±4.67	0.877
Intra group analysis Difference			
• 0d-15d	+0.30	-	-
• 0d-30d	+0.65	-	-
• 0d-45d	+0.90	+0.10	-
• 0d-60d	+1.70	+0.10	-
P value			
• 0d-15d	0.083+	-	-
• 0d-30d	0.008**	-	-
• 0d-45d	0.025*	0.343	-
• 0d-60d	0.001**	0.343	-

Test used:

Student's 't' test (unpaired) for intergroup analysis and Student's 't' test (paired) for intra group analysis. T_0 day vs T_{60} day ($p<0.001$), C_0 day vs C_{60} day ($p>0.05$), C_0 day vs T_{60} day ($p<0.001$).

Ageing process is associated with the increased formation of free radicals which are responsible for starting the degenerative process during aging. This is the main cause of memory impairment in the old age. Oxidative stress directly damages cell components, resulting in damage to

synapses and nerve cell death. Antioxidants are thought to act against neurodegeneration by limiting the production of toxic substances and by reducing damage by free radicals. [36] Furthermore, there are relatively fewer antioxidant enzymes specifically focused on neuronal protection, suggesting that antioxidant nutrients may have a more prominent role in older and ageing brains than in other organ systems. [37] Our test formulation (*Majoon Falasfa*) contains various ingredients which are brain tonics, nervine tonics and is endowed with anti-oxidant properties viz Filfil daraaz *(Piper longum)*, Zanjabeel *(Zingiber Officinale),*[38] Amla *(Emblica officinalis),*[39] Balela *(Terminalia bellerica),*[40] Babuna *(Matricaria chamomillia),*[41] Darchini *(Cinnamomum zeyanicum),*[42] Sheetraj *(Plumbago Zeylanicum),*[43] and Narjeel *(Cocus nucifera).* [44] Aeschbach *et al* reported the anti-oxidant effect of 6-gingerole and gingerone contained in *zanjabeel (Zingiber Officinale)*. Studies also showed Amla *(Emblica officinalis)* to possess adaptogenic activity (Rege *et al*) and anti-oxidant activity of its constituents i.e. Amblicanin A and B (Shibnath *et al*). Furthermore, stilbenes contained in Maweez *(Vitis vinefera)* also have got anti-oxidant effect (Toguo *et.al*).[45,46,47,48] These ingredients are included in the formulation and the action of memory enhancement in the aged people might be attributed to them. Furthermore, according to the study done by Saka B *et al*, depression, dementia, functional dependence and multiple co-morbidities were associated with poor nutritional status. Since our test drug improves the nutritional status in elderly as discussed above, thus this might be one of the contributing factors for improvement in dementia score in this study.[49]

In present study when Mean ± SD data of physical activity score and Hb% were compared statistically the results were found insignificant (Table 6 & 7). However, clinically there was improvement in haemoglobin level in patients of test group. Improvement in haemoglobin content in test group might be due to *Muallid dam* (Haematinic) activity of Maweez Munaqqa *(Vitis vinefera)* and Filfil Daraaz *(Piper longum).*[30] Furthermore, test drug improves the digestive functions, resulting in increase in appetite and food intake, which in turn results in improvement of nutritional status in elderly. Saka B *et al* confirmed that patients with poor nutritional status had lower blood haemoglobin, total serum protein and albumin, and revealed more chronic diseases and geriatric syndromes. The possible reason for non-improvement in physical activity score might be due to enrolment of those elderly persons who were ambulatory and presented with minor geriatric problems. Regarding physical activity, it would have been better to assess the efficacy of test drug in bed- ridden or crippled patients. To determine the adverse effects of test drug, safety parameters like LFT, RFT and blood sugar (Table 8) were carried out at baseline and at the end of the treatment. After completion of duration of treatment all safety markers were

found within the normal limits suggesting that it can be safely used at described therapeutic dose. Thus it can be stated that the test drug is safe and effective in elderly and can be used prophylactically to counter the effects of ageing.

Table 6: Comparative Evaluation of Haemoglobin % in two groups at different time points

Haemoglobin %	Group 1	Group 2	P value
0d	13.33±1.59	13.60±0.93	0.620
15d	13.50±1.70	13.57±2.08	0.917
30d	13.64±1.73	13.78±1.89	0.836
45d	13.13±1.52	13.46±1.89	0.604
60d	13.74±1.86	13.77±1.70	0.966
Intra group analysis			
Difference			
• 0d-15d	+0.17	-0.03	-
• 0d-30d	+0.31	+0.18	-
• 0d-45d	-0.20	-0.14	-
• 0d-60d	+0.42	+0.17	-
P value			
• 0d-15d	0.468	0.949	-
• 0d-30d	0.158	0.604	-
• 0d-45d	0.584	0.786	-
• 0d-60d	0.130	0.576	-

Test used:

Student's 't' test (Independent) for intergroup analysis and Student's 't' test (dependent) for intra group analysis. The results are insignificant in both groups ($p>0.05$).

Table 7: Comparative Evaluation of Physical Activity Score in two groups at different time points

Physical Activity Score	Group 1	Group 2	P value
0d	5.85±0.37	5.20±1.40	0.058+
15d	5.85±0.37	5.40±0.97	0.074+
30d	5.85±0.37	5.40±0.97	0.074+
45d	5.95±0.22	5.40±0.97	0.020*
60d	5.95±0.22	5.70±0.67	0.140
Intra group analysis			
Difference			
• 0d-15d	0.0	+0.20	-
• 0d-30d	0.0	+0.20	-
• 0d-45d	+0.10	+0.20	-
• 0d-60d	+0.10	+0.50	-
P value			
• 0d-15d	-	0.343	-
• 0d-30d	-	0.343	-
• 0d-45d	0.163	0.343	-
• 0d-60d	0.163	0.244	-

Test used:

Student's't' test (Independent) for intergroup analysis and Student's 't' test (dependent) for intra group analysis. The results are insignificant in both groups ($p>0.05$).

Table 8: Safety profile

Blood urea	**BT**	**AT**	**P value**
Group 1	30.55±2.11	31.15±3.23	0.387
Group 2	31.40±5.74	29.50±10.46	0.578
P value	0.577	0.518	-
Serum creatinine	**BT**	**AT**	**P value**
Group 1	0.92±0.08	0.93±0.13	0.871
Group 2	0.94±0.12	0.93±0.16	0.847
P value	0.593	0.925	
SGOT	**BT**	**AT**	**P value**
Group 1	23.15±8.37	21.85±7.23	0.461
Group 2	22.50±5.04	22.80±10.14	0.871
P value	0.824	0.769	-
SGPT	**BT**	**AT**	**P value**
Group 1	20.65±8.72	19.45±6.76	0.622
Group 2	23.30±10.41	23.80±17.6	0.868
P value	0.468	0.334	-
Blood Glucose(mg/dl)	**BT**	**AT**	**P value**
Group 1	103.30±17.85	107.40±16.30	0.376
Group 2	104.40±14.77	105.90±14.87	0.713
P value	0.868	0.809	-

CONCLUSION

The study revealed that the test drug appeared to be efficacious in the geriatric problems and exhibited significant effects in improvement of weight, grip strength score, appetite score and dementia score. Hence it can be said that this intervention can have a major impact on the patient and family's well being and on the cost of long term care. No adverse effects or toxicity has been reported during or after the trial. Thus, it can be stated that the test drug is safe and effective in elderly to promote their health and can be used prophylactically to counter the effects of ageing.

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