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CLINICAL RESPONSE AND SAFETY OF MENERGY®, DIETARY SUPPLEMENT CAPSULE (MDSC) FOR MALE SEXUAL LIFE IMPROVEMENT

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ABSTRACT

Background and aim: Male sexuality, a complicated bodily process, is an essential aspect of a man's well-being and happiness. Globally, multiple treatments (allopathic, ayurvedic, and homoeopathic) are available for improving men's sexual life, however, either they are ineffective or have unfavorable adverse effects that have an impact on a person's general health. The goal of the current clinical trial was to assess the effects and safety of MENERGY, a dietary supplement capsule (MDSC), on men's sexual life, vitality, sexual satisfaction, and pleasure during intercourse and enhance libido and improve individual sexual health. **Material & Methods:** It was a multi-center, prospective study on Pakistani men that was carried out in collaboration with a leading tertiary care facility, Hamdard Institute of Karachi, Pakistan. The study was conducted for six (6) Months from 2nd May 2021 to 31st October 2021. The study inclusion criteria selected 55 married males, 21 years and above, who engaged in frequent sexual activity. The international standard for clinical practice (GCP-E6) was followed in the compilation of the study. The selected subjects were follow-up for 8 weeks treatment (visit -1 and visit -2), requested to complete the design Case Report Form (CRF) on the sexual disorders and respond to the specific questionnaires i.e., SQoL-M for sexual dysfunction and IIEF score for erectile dysfunction. The safety report was recorded in the WHO recommended safety reporting form (CIOMS form I). **Results:** The study's findings presented a considerable improvement in erection quality, erotica, and mood. Memory, endurance, and anxiety all showed mild to significant improvement. No major adverse events related to medication have been documented. **Conclusions:** Compared to other accessible Ayurveda, allopathic, and homoeopathic medications, the Menergy (MDSC), which was made up of quality innovative herbal ingredients, vitamins, and minerals, supported men's sexual life, vigour, and wellbeing with negligible adverse effects.

KEYWORDS: Male sexual dysfunction; Sexual Quality of life; Dietary Supplement Capsule; Pakistani Population.

INTRODUCTION

Male sexuality, a complicated bodily progression, is an essential aspect of a man's well-being and happiness.[1] In the male, the Sexual Medicine's Second International Consultation defined male infertility is characterized by a persistent inability to engage in normal sexual activity due to premature ejaculation, delayed or inhibited ejaculation, erectile dysfunction, problems with arousal (lower libido), obsessive sexual behavior, orgasmic disorder, and failure to ovulate.[2] Among Sexual Dysfunction (SD), Erectile Dysfunction (ED) is one of the ancient complaints, afflicting 52 per cent of 40- to 70-year-old men and is expected to reach 320 million by 20251.[3] It is still one of the most common and under-recognized illnesses among sexual disorders libido (desire), erectile function, and sexual activity make up the three phases of the male sexual response cycle.[3] Anything that alters the sexual response cycle, from psychological causes to surgery or trauma to vascular illness or neurological problems, might result in sexual dysfunction.[2-4] In addition, a variety of variables have been linked to an increased risk of Sexual Dysfunction in males, including a sedentary lifestyle, high levels of stress, different chronic illnesses, various toxins in the environment, and various pharmacological side effects.[1-4] Sexual disorders have been linked to the usage of a wide range of widely prescribed medications, as impotency is often linked to anti-hypertensive medications.[5,6] The prevalence of cardiovascular diseases, high cholesterol, diabetes, chronic renal

disease, or cancer of the reproductive system may lead to SD. Overall, to maintain sexual function, a person's multi-system has to be coordinated.[7-10] This includes coordination of the neurological system with the cardiovascular, endocrine and reproductive systems.[7-10] Normal sexual quality of life will suffer if the underlying system or psychological factors are altered.[11] Therefore, the management of sexual dysfunction must be accompanied by psychological and social input.[11] It was during the 1990s when sildenafil was first authorized by the FDA as a treatment for erectile dysfunction.[12] While herbal products are still used in many regions and nations in an ad hoc manner, and a sizable portion of medicinal plants used traditionally to treat male reproductive disorders have not yet undergone scientific evaluation in many regions and countries around the world, patients with SD have used traditional medicines or herbal drugs with varying degrees of success.[13,14] MENERGY (Dietary Supplement Capsule, MDSC) is a product of choice for male sexual life improvement and vitality. The existing formulation is based on a blend of herbs, vitamins and micronutrient ingredients known individually for their application in male sexual improvement and quality.[15] The combination of herbs being used in the preparation of MENERGY are used in traditional herbal medicinal systems and ayurvedic medical systems individually and in combination since medieval times for men's health, sexual debility, nervous weakness, improve spermatogenesis, premature ejaculation and thinness of the semen, improved stamina and lively hood. All ingredients are mild, and aphrodisiacs are further enhanced with vitamin B1, Vitamin B6 and micro-nutritional elements Zinc and Selenium, well tolerated as reported in literature.[16-18] Additional adding commonly called Holy Basil (Tulsi), Ocimum sanctum (synonym – Ocimum tenuiflorum), that may boost sex life, can help increase circulation, stimulate the sex drive and boost fertility.[19] Menergy also adds *Tamarindus indica* (chian seeds), known for high antioxidant activities actively used in food products, industries, and medicine.[20] Another addition includes *Curculigo orchioides* (Golden eye, Siah Musli), known to manage erectile dysfunction due to its aphrodisiac properties.[21] It increases sexual desire and helps to maintain the erection during intercourse.[22] It also helps increase the male potency as it has spermatogenic property.[22] This helps improve the sperm quality as well as the sperm count.[21-22] For male infertility, *Withania somnifera* (Ashwagandha) and *Anacyclus pyrethrum* (Akarkara) include in Menergy that may help in restoring a good sex life.[23,24] First, it helps in the production of testosterone.[23,24] It increases the serum levels of the luteinizing hormone and testosterone and revitalizes the natural balance of sexual hormones in men.[23,24] In another addition, *Panax ginseng* contributes to physical and mental well-being and supports energetic alertness.[25] Menergy has a strongly favorable effect on men's libido and sexual satisfaction, according to undocumented accounts and preclinical research studies. Notably, no substantial or serious problems have been documented in preclinical studies as a result of Menergy usage. As a result, the current study was designed on humans to assess the efficacy, and safety of Menergy and to determine the improvement in males' quality of life and vitality.

MATERIALS AND METHODS

Preparation and physicochemical characterization of (MDSC) Dietary Supplement ingredients.

Preparation of materials

The vitamins, minerals and herbal ingredients were obtained from qualified resources with a certificate of analysis, (Table 1). Vitamin B1, vitamin B6, Zinc and Selenium complied with USP-42 pharmacopoeia. The herbal extracts were tested for their physical appearance, odour, bulk density, identification, foreign matter, total ash, moisture content, solvent residue, heavy metals (Arsenic, lead, cadmium and mercury), microbiological data including total plate count, yeast and molds, *E. coli*, Salmonella and *Staph aureus.* Pesticide residues complied with EU Regulation 396/2005 and USP. All herbs were tested as per Indian pharmacopoeia except, *Withania somnifera* and *Panax ginseng* as per USP-42. The required amount of individual herbal extracts, vitamins and minerals were blended and filled in 00-size HPMC capsules free from Transmissible Spongiform Encephalopathy 9TSE) and Bovine Spongiform. Encephalopathy (BSE) and compliant with US FDA colour codes. Each capsule weighs around 700 mg. Finally, 60 capsules were transferred into food-grade HDPE bottles and kept on stability.

Table 1: Characteristics of ingredients of (MDSC) Dietary Supplement Ingredients: Vitamins, minerals, and herbal extracts proper name and common name.

Proper Name	Common Name
Thiamine	Vitamin B1
Pyridoxine	Vitamin B2
Zinc	Zinc
Selenium	Selenium
Ocimum sanctum (synonym – Ocimum tenuiflorum (tenuiflorum	Holy Basil, Tulsi
Tamarindus indicum	Tamarind gum
Curculigo orchioides	Golden eye-grass
Withania somnifera	Ashwagandha
Anacyclus pyrethrum	Spanish Chamomile
Panax ginseng	ginseng

Determination of MENERGY Dietary Supplement Capsule (MDSC) contents

Vitamin B1 and Vitamin B6 were determined by the HPLC method. The contents of Zinc and Selenium were determined by atomic absorption spectroscopy. The contents of the premium herbal blend were determined by HPTLC and by GC-MASS.

Stability Studies of MENERGY Dietary Supplement Capsule

The objective of the study (MDSC) is the assessment of the stability profile under real-time conditions and stress conditions on a long-term basis, Table 2 and Table 3. The long-term stability studies are being conducted for a period of shelf life i.e., 24 months plus one year on the selected batches. The samples are tested initially and are being tested after every 3rd month over the first year and after the 6th month over the second year and after that annually through the proposed shelf-life plus one year for the following parameters: Note: Microbial test performed only at initial, 6th, 24th and 36th month.

Table 2: Demographics details.

Age	40.33±(9.13)	
Weight	74.39±(13.0)	
Allergy (Y/N)	2(3.8%)/51(96.2%)	
Pulse rate (Normal)	100%	
Heart Rate (Normal)	100%	
Blood pressure (Normal/raised)	49(92.5%)/4(7.5%)	
Smoking (Y/N)	14(26.4%)/39(73.6%)	
Non -Alcohol	100%	
Presenting complaint	Impotent	2(3.8%)
	Less semen	8(15.1%)
	No Erection	11(20.7.9%)
	Soft Erection	24(45.2%)
	Unable to complete Act	8(15.1%)

Table 3: Sexual Health Inventory Score and Its Severity (Pre and post Treatment).

Mean		**Pre-treatment**		**Post Treatment**		**P-value**
Sexual Health Inventory Score		15.28±3.53		21.24±2.84		0.00*
Sexual Health Inventory Score Pre-treatment		Severity of Sexual Health Inventory Score Post-treatment				
		No ED	Mild	Mild to Moderate	Severe ED	
Severity of Sexual Health Inventory Score	Mild n=22	20(90.9%)	2(9.1%)	0(0%)	0(0%)	0.00
	Mild To Moderate n=24	6(25.0%)	17(70.8%)	1(4.2%)	0(0%)	
	Moderate ED n=6	2(33.3%)	3(50%)	1(16.7%)	0(0%)	
	Severe ED n=01	0(0%)	0(0%)	1(100%)	0(0%)	

Safety Assessment (MDSC) Acute Toxicity Study in Animals

The acute toxicity test was performed at H.E.J. Research Institute of Chemistry, International Center for Chemical & Biological Sciences, University of Karachi, Karachi-75270, Pakistan. Young healthy male Sprague Dawley (SD) rats weighing 145-175 g were used. The temperature and relative humidity of the animal room was maintained at 22°C ± 1°C and 30% to 70%, respectively. Illumination was controlled with a 12 h dark and 12 h light cycle. All animals received sterilized water prepared by using an Aqua-guard RO filter. Animals were fed a standard pellet diet. All the above conditions were maintained throughout the experiment. All ethical practices were followed while performing experiments on animals. Rats were randomly distributed into three groups i.e., GI to GIII with 6 animals in each group. The test sample was orally administered. Animals were then carefully observed for 5 hours to monitor any possible changes in their gross behaviors, mood, motor activity pattern, signs of morbidity and mortality. The subsequent observations were made after 24 hours. Animals were given free access to water and food throughout the study. Drugs Administration (MDSC) was administered orally in test animals (rats).

Macroscopic clinical signs were recorded for 5 hours after administration of the drug and the last observation was made after 24 hours.

Study Design

It was a multi-centre, prospective study on the Pakistani male gender conducted in collaboration with a leading tertiary care hospital, Hamdard Institute of Karachi, Pakistan. The study was conducted for 6 Months from 2nd May 2021 to 31st October 2021. The study inclusion criteria were male and married, having the age of 21 years and above with regular sexual activity. The exclusion criteria included the refusal to give consent for the study, any Psychiatric illness, sexually transmitted diseases and spinal injury and major pelvic surgeries. The selected 55 subjects were follow-up for 8 weeks of

treatment (visit -1 and visit -2), requested to complete the design Case Report Form (CRF) on the sexual disorders and respond to the specific questionnaires i.e., SQoL-M for sexual dysfunction and IIEF score for erectile dysfunction.

Outcome

The main outcome was sexual experience assessed by the Sexual Quality of Life for men (SQoL-M) questionnaire and Sexual Dysfunction assessed by the International Index of Erectile Function (IIEF)-Score for Erectile Dysfunction.

Study Plan

The participants were requested to sign the consent form and complete the design questionnaire following the in-person interview, evaluation of the volunteers' eligibility for participation in the study, and presentation of the interviewer's complementing explanations. The International Index of Erectile Function (IIEF)-Score for Erectile Dysfunction and the CRF with the Sexual Quality of Life for Men (SQoL-M) questionnaire. Afterwards, the Menergy was prescribed to the individuals. The questionnaire was filled out by the participants twice: once at the study's beginning (Baseline Visit-1), and once again three months later (visit-2). For Menergy, the subjects were counselled to consume Menergy for 7-12 hours prior to sexual intercourse. Safety Assessment of Menergy (MDSC): Before the study, all volunteers were informed about the possible benefits and adverse effects of the (MDSC) Dietary Supplement. The participants were provided with a checklist of possible major, minor and critical adverse effects to be followed and reported immediately on a given contact number of the relevant study members. In case of any adverse event, the safety report is recorded in WHO- CIOMS form me of Adverse event.

Ethics approval and consent to participate

The international standard for clinical practice (GCP-E6) was followed in the compilation of the study, prior to initiation, the ethics review committee approved the study and informed consent was taken from all recruited subjects. The Ethical approval was obtained from Hamdard University's ethical Committee on Ethics (Reference no: HAM/EC/CS/28-04-2021-01). The patients were enrolled after signing informed consent.

Statistical analysis

A consecutive non-probability sampling technique was adopted. A total of 55 male patients of both genders and aged 21 years or above were registered for sexual life improvement among the Pakistani population. For data entry and analysis, SPSS version 21.0 for Windows (IBM Corp., Armonk, NY) was utilized. Mean and standard deviation (SD) were calculated for quantitative variables like age. Frequency and percentages. Post-stratification Chi-square test was applied, and OR was calculated with 95% CI. P-value ≤ 0.05 was taken as statistically significant.

RESULTS

Pre-clinical results: safety assessment (MDSC) Acute Toxicity Study in Animals

Oral administration of (the MDSC) Dietary Supplement did not produce any signs of acute toxicity nor demonstrated lethality at doses of 0.5 gm, 1 gm. and 5 gm. in SD rats. Throughout the observation time, every animal lived. At the conclusion of the observation period, none of the animals had lost weight. All of the animals exhibited no harmful symptoms.

Clinical results

The study was completed by 55 male participants. The mean age of the participants was 40.33±(9.13) years with a weight of 74.39±(13.0). The vitals were normal with Blood pressure (Normal/raised) being 49(92.5%)/4(7.5%) respectively. The majority of males were smokers (39, 73.6%). The male subjects with sexual dysfunction were mainly the problem of soft erection (24, 45.2%) followed by no erection (11, 20.7.9%) rest were unable to completely act (8, 15.1%), less semen (8,15.1%) and impotence (2,3.8%) respectively. The details are mentioned in Table 2.

In the case of Sexual Health Inventory (IIEF) score for erectile dysfunction (score: no ED: 22-25, Mild: 17-21, Mild Moderate: 12-16, Moderate: 8-11 and Severe:1-7), overall improvement in IIEF score from the base visit (15.28±3.53) to the follow-up visit after the treatment with capsule Menergy (21.24±2.84). The details of the IIEF score are mentioned in Table 3.

In the study participant subject's sexual quality of life that assessed by the Sexual Quality of Life Questionnaire- Male (SQoL-M). In the questionnaire, a total of eleven (11) relevant questions were asked to the subjects before the start of study treatment (Baseline Visit) and repeated the questionnaire after the treatment follow-up (visit -2). As a result, an overall improvement in individual sexual quality of life with a positive response in all eleven questions. The details of SQoL-M are mentioned in Table 4.

Table 4: Sexual Quality of Life Questionnaire- Male (SQoL-M).

Questions (SQol-M)	Pre-treatment	Post-treatment			
		Completely Agree	Moderately Agree	Slightly Agree	p-value
About my sexual life, frustrated (n=53)	Completely Agree (n=28)	2(7.1%)	26(92.8%)	0	0.00
	Moderately Agree (n=25)	0(0%)	8(32%)	17(68%)	
2. About my sexual life, depressed (n=53)	Completely Agree (n=30)	10 (33.3%)	20(66.66%)	0	0.00
	Moderately Agree (n=23)	0	7(30.4%)	16(69.56)	
3. About my sexual life, less of man (n=53)	Completely Agree (n=15)	4 (26.5%)	11(73.3%)	0	0.00
	Moderately Agree (n=38)	0	8(21.05)	30(78.9%)	
4. Lost confidence in myself as a sexual partner (n=53)	Completely Agree (n=15)	6(40%)	9(60%)	0	0.00
	Moderately Agree (n=38)	0	12 (31.5%)	26 (68.4%)	
5. About my sexual life, anxious (n=53)	Completely Agree (n=15)	4 (26.5%)	4 (26.5%)	0	0.00
	Moderately Agree (n=37)	0	5 (13.5%)	32 (86.4%)	
6. About my sexual life, angry (n=53)	Completely Agree (n=10)	5 (50%)	5 (50%)	0	0.00
	Moderately Agree (n=40)	0	18(40.9%)	22 (55%)	
	Slightly Agree (n=4)	0	0	4(100%)	
7. Worry about the future of my sexual Life (n=53)	Completely Agree (n=10)	0	10 (100%)		0.00
	Moderately Agree (n=34)	0	30 (88.2%)	4 (11.7%)	
	Slightly Agree (n=09)	0	0	9 (100%)	
8. About my sexual life, embarrassed (n=53)	Completely Agree (n=15)	05 (33.3%)	10(66.5%)	0	0.00
	Moderately Agree (n=28)	0	08(28.5%)	20(71.4%)	
	Slightly Agree (n=10)	0	0	10 (100%)	
9. About my sexual life, guilty (n=53)	Completely Agree (n=09)	01 (11.1%)	08 (88.8%)	0	0.00
	Moderately Agree (n=34)	0	30 (88.2%)	4 (11.7%)	
	Slightly Agree (n=10)	0	0	10(100%)	
10 About my sexual life, worry my partner feels hurt or rejected (n=53)	Completely Agree (n=15)	05 (33.3%)	10(66.5%)	0	0.00
	Moderately Agree (n=26)	0	15 (57.6%)	11(42.3%)	
	Slightly Agree (n=12)	0	0	12 (100%)	
11. About my sexual life, lost something (n-53)	Completely Agree (n=15)	07(46.6%)	08 (53.3%)	0	0.00
	Moderately Agree (n=18)	0	10 (55.5%)	8 (44.4%)	
	Slightly Agree (n=20)	0	0	20 (100%)	

Safety Assessment of (MDSC) on real-time subjects

During the study, no adverse drug reaction (ADR) was reported. The subjects reported 04 mild Adverse Events (AEs) including gastric irritation (n=3) and palpitation (n=1). These subjects are known cases of hypertension and arthritis with a history of antihypertensive drugs and Non-Steroids Anti-Inflammatory (NSAIDs) drugs.

DISCUSSION

The results of the present study indicate that Menergy has a positive impact on men's sexual experiences and enhances a number of sexual functions, including desire, arousal, orgasm, erection, and satisfaction. Menergy was tested clinically as a whole preparation in this study. The research on Menergy was supported by multiple studies on herbal interventions (single and in combination), non-herbal nutraceuticals, mixed herbal and non-herbal nutraceuticals, and topical herbal applications. In the composition of Menergy, herbaceous plant (Korean ginseng) is an important component of Menergy.[25] Korean ginseng is a traditional Chinese medicine that has been used for hundreds of years as an aphrodisiac to enhance sexual performance.[26] For male reproductive disorders, poor sexual performance, and erectile dysfunction, *Panax ginseng* is a well-liked foreign flavoring supplement.[26] The present research confirmed the outcomes of four studies on *Panax ginseng*, three of which found positive results and one of which found no differences.[27] Bursik, et al. study results, contribute the support of *Panax ginseng* to physical and mental well-being, support alertness and improves men's reproductive cycle.[28] The literature review based 7 studies on Korean ginseng supporting the effective and alternate approach for the treatment of erectile dysfunction.[20] De Andrade E, et al. also endorsed in their study data that Korean ginseng can be an effective alternative for improved erectile performance.[29] The Menergy compose of vitamins including Thiamine (Vitamin B1), and Pyridoxine (Vitamin B6) both vitamins help in energy metabolism, and tissue formation, help to form red blood cells, regulate hormonal activity, reduce fatigue and help to maintain the body's ability to metabolize nutrients.[16] The Menergy contain important minerals including Zinc and Selenium. Selenium (Se) as a component of Menergy is primarily required for spermatogenesis and male fertility, according to findings from previous studies (both animal and human), owing to its critical function in modulating antioxidant defense systems, other crucial metabolic pathways, and redox-sensitive transcription factors.[30,31] An increasing amount of research on putative molecular pathways in males suggests that selenium (Se) has a structural role in sperm, which may have an impact on sperm motility, chromatin integrity, and fertility rate. This role is mediated by a distinctive and canonical selenoprotein known as GPX4.[30,31] The zinc that is available aids in the creation of connective tissue, maintains healthy skin, supports immune system function, aids in energy metabolism, and maintains healthy bones, skin, hair, and nails., and prevents zinc deficiency to maintain the body ability to metabolize nutrients, helps fertility, reproduction and maintains the optimum level of testosterone.[16,17] Importantly, the Menergy contain herbs including, commonly called as Holy Basil or Tulsi, Ocimum sanctum (synonym – Ocimum tenuiflorum), *Tamarindus indica*, *Curculigo orchioides*, *Withania somnifera* and *Anacyclus pyrethrum*. From the research, Holy Basil (herb) may stimulate the sex drive and boosts fertility with improved sperm count and serum sex hormone, Geno protective and antioxidant.[19] In another study, one hundred volunteers aged 18–65 years received either 125mgof *Ocimum tenuiflorum (Holy Basil)* twice daily or a placebo. Outcome measures included the Perceived Stress Scale (PSS) (primary outcome measure), Profile of Mood States, Athens Insomnia Scale (AIS), Restorative Sleep Questionnaire, and the Patient-Reported Outcomes Measurement Information System-29. Sleep quality was also assessed using a wrist-worn sleep tracker (Fitbit), and stress changes were examined by measuring between-group differences in hair cortisol and stress responses after exposure to an experiment stress procedure known as the Maastricht Acute Stress Test (MAST). Compared to the placebo, *Ocimum tenuiflorum supplementation* was associated with greater improvements in PSS (p = 0.003) and AIS (p = 0.025) scores; and at week 8, concentrations in hair cortisol were also lower (p = 0.025). Moreover, *Ocimum tenuiflorum* supplementation was associated with a buffered stress responses after exposure to the MAST as demonstrated by significantly lower concentrations in salivary cortisol (p = 0.001), salivary amylase (p = 0.001), systolic (p = 0.010) and diastolic (p = 0.025) blood pressure, and subjective stress ratings (p < 0.001). *Ocimum tenuiflorum* supplementation was well-tolerated with no reports of major adverse effects. (49).The biochemical, hematological, and histological alterations in tissues (liver, kidney, spleen, heart, and testis/ovary) were identified during the preclinical study on *Holy Basil* (herb) to evaluate the acute (14 days) and subacute toxicity of the herb.[32] The *Holy Basil* (herb) did not produce any hazardous symptoms or death and CNS and ANS toxicities in the acute toxicity test.[32] There was no difference in body weight, food and water intake, or hematological and biochemical profiles following the subacute therapy with OSE.[32] In addition, no change was observed both in macroscopic and microscopic aspects of vital organs in rats.[32] Our study on humans supports the preclinical results showed that *Holy Basil* extract proved to be safe for human.[33] Similarly, *Tamarindus indica* supports and acts as an antioxidant, anti-inflammatory, aphrodisiac, increases sperm count and reduces premature ejaculation.[34] The preclinical study *Tamarindus indica* assess the chronic toxicity for the duration of 6 months duration, in the study there were no abnormalities in hematology and blood biochemistry parameters caused by long-term herb administration.[34] This study showed that long-term use was generally safe and well tolerated at the tested dose.[34] In the case of *Curculigo orchioides* (herb), the research support it may

reduce erectile dysfunction, increases sexual desire, spermatogenic, immunity booster, antioxidant and neuroprotective.[21,22] In the preclinical study on *Curculigo orchioides* to assess neurotoxicity, the study showed that the herb is a rich source of phytochemicals like flavonoids and polyphenols.[35] Flavonoids and polyphenols are reputed to demonstrate neuroprotective effect.[35] In the study, phytochemicals were responsible to demonstrate a neuroprotective effect.[35] Our study showed no neurotoxic effects were reported on human subjects. *Withania somnifera* and *Anacyclus pyrethrum* both herbs increase libido & testosterone levels, improve sperm count, and physical performance with improves memory & immunity. A past safety study on a human was conducted on *Withania somnifera* herb, the study showed that the formulation was found to be safe on hematological and biochemical organ function tests. The study also showed increased sleep safety, cholesterol reduction, and muscular building. In the case of *Anacyclus pyrethrum*, the preclinical study to evaluate the acute toxicity of the herb.[36] The results of the study indicate that the *Anacyclus pyrethrum* was not toxic.[36] The previous studies demonstrated the major impact of sexual engagement on men's quality of life, and it is an important component of social functioning.[37-39] The Sexual Health Inventory is a frequently used questionnaire for evaluating Erectile Dysfunction (ED) and is recommended by American Urological Association standards.[40] According to previous research, ED is more prevalent in older people and is linked to comorbid conditions such diabetes, hypertension, and chronic renal disease.[41,42] In our study, the average Sexual Health Inventory Score was 15.283.53; following 8 weeks of study drug therapy, there was a considerable improvement to 21.242.84 on the scale. Prior research studies' findings indicated that individuals with sexual dysfunction had a worsened quality of life and were linked to a number of diseases.[43-47] Even temporary interference in sexual activities can be distressful and chronic stage can impair relationship between the couple lead to anxiety, depression and other psychological problems that disrupt functioning in other aspects of life.[39] The current study assessed the sexual Qol of the recruited patients by Sexual Quality of Life Questionnaire- Male (SQoL-M).[48] Before the treatment, the subjects complaining the similar problems of anxiety, depression, frustration, anger, embarrassment, and relevant issues as part of the questionnaire. After the study treatment, overall positive response received from the subjects.

CONCLUSIONS

The Menergy (MDSC) composed of premium novel herbal ingredients, vitamins and minerals showed significant support in men's sexual life, vitality and wellbeing with insignificant adverse effects among other available ayurvedic, allopathic and homoeopathic medicines. Respecting the cultural and religious boundaries of the patients help create a trustworthy and cooperative environment which ultimately leads to increased patient satisfaction and improved outcome.

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Disclosures

Potential conflicts: The authors have no conflict of interest.

Author's Contribution

Author 1: Formulation preparation, uses & benefits, safety and toxicology scientific research, Stability studies, acute toxicology studies and chronic toxicology studies

Author 2: Principal Investigator, Site data collection and management & execution

Author 3: Protocol development, manuscript writing, publication, and statistical analysis

Author 4: Analytical work of MENERGY Dietary Supplement ingredients and Finished Product

Author 5: Safety, toxicology research, Stability studies, acute toxicology studies and chronic toxicology studies

Author 6: Study coordinator and site data collection.

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