World Journal of Biology Pharmacy and Health Sciences
eISSN: 2582-5542
Cross Ref DOI: 10.30574/wjbphs
Journal homepage: https://wjbphs.com/

(RESEARCH ARTICLE)

Check for updates

Clinical validation of safety and effectiveness of De-Stress and Perform Tablet

Sachin Baburao Mulik [1], Kriti Soni [1,*] and Gayatri Pramod Ganu [2]

[1] *R & D, Herbolab India Pvt. Ltd., 3rd Floor - A Wing, Marwah Centre, Krishanlal Marwah Marg, Marol, Andheri East Mumbai, Maharashtra, India, 400072.*
[2] *Director, Mprex Healthcare Pvt. Ltd., Office Number 501, 514 Crossroads, Bhumkar Square, Wakad, Pune, Maharastra, India, 411057.*

World Journal of Biology Pharmacy and Health Sciences, 2025, 21(02), 008–016

Publication history: Received on 25 November 2024; revised on 04 January 2025; accepted on 06 January 2025

Article DOI: https://doi.org/10.30574/wjbphs.2025.21.2.1058

Abstract

Introduction: Numerous physical and mental health issues have been linked to stress, making it a major global health concern. Natural alternatives have the ability to lessen stress and enhance brain function. This study aims to establish clinical proof of De-Stress & Perform Tablet's efficacy and safety.

Materials and Methods: An open-label, non-randomized study was conducted on thirty healthy male subjects. Each subject received one bottle containing 30 De-Stress & Perform tablets for 30 days. The research objectives were to evaluate changes in CBC (Complete Blood Count), LFT (Liver Function Test), and RFT (Renal Function Test) parameters, sexual desire using the Sexual Desire Inventory (SDI) score, Perceived Stress Scale (PSS) score, and self-reported stamina on a 4-point Likert scale were evaluated at screening and day 30.

Results: After 30 days of treatment, white blood cell (WBC) count, creatinine, and uric acid levels decreased, while Mean Corpuscular Hemoglobin Concentration (MCHC) and urea levels increased; these changes were statistically significant but clinically insignificant. Other hematological and liver function parameters remained within normal ranges, with no statistically or clinically significant changes. Vital signs were stable, perceived stress decreased by 61.35% ($p < 0.001$), self-reported stamina improved, and sexual desire increased by 62.34% ($p < 0.001$). All participants demonstrated excellent tolerability, and no adverse events were attributed to the investigational product.

Conclusion: The De-Stress & Perform Tablet was well-tolerated and safe in healthy males, with no clinically significant adverse effects. It also demonstrated efficacy in reducing stress, enhancing stamina, and increasing sexual desire.

Keywords: De-Stress and perform tablet; Perceived stress; Safety; Efficacy; Sexual Desire Inventory; Nutraceutical

1. Introduction

During World War II, pilots and submarine crew members were administered various stimulants, which led to the development of the theory that a pill might enhance both mental and physical performance in healthy individuals [1,2]. For example, the earliest research on Schisandra chinensis's stimulating and tonic properties was published in military journals of the Soviet Union during World War II. The ethno-pharmacological studies conducted in the Far East by Komarov (1895) and Arsenyev (1903–1907) sparked Russian interest in S. chinensis. It was found that Nanai (Goldes or Samagir) hunters used the berries and seeds as a tonic, to lessen hunger, thirst, and tiredness, and to enhance night vision. In the 1950s and 1960s, the concept of using herbal remedies to boost resistance to disease and prolong life in hazardous [3]. In a recent survey conducted in the Boston area, 52% of males aged 40 to 70 had some level of erectile dysfunction (ED). Enhanced sexual behaviour may bring increased relationship pleasure and self-esteem in humans [4].

* Corresponding author: Kriti Soni

An array botanicals have been demonstrated to substantially impact sexual functions, reinforcing previous assertions and raising hopes in the process. This review reveals a range of botanicals that may be helpful in treating sexual dysfunction while assessing the numerous aspects that govern sexual function. Every plant included in this review has demonstrated a notable level of pharmacological action. Studies on the effects of natural aphrodisiacs on humans and their safety profile are becoming more and more necessary due to demand [4,5].

The Ashwagandha herb (*Withania somnifera*, also known as Indian Ginseng or Winter Cherry) has been linked to numerous potential health benefits in both traditional Ayurvedic and modern medical literature [6]. These benefits fall under the categories of anti-stress, immunomodulatory, anti-tumour, and rejuvenating effects [7]. The herb also interacts with the nervous system, endocrine system, cardiopulmonary system, energy production system, and immune system, producing analgesic, antimicrobial, anti-inflammatory, anti-tumour, anti-stress, anti-diabetic, neuroprotective, immune protective, and cardio protective effects [8]. Exogenous l-arginine intake has been shown in a number of human and experimental animal studies to have numerous positive pharmacological effects when taken at amounts higher than typical food consumption. These benefits include improved erectile dysfunction as well reduced risk of heart and vascular conditions [9]. Both systemic and cerebral circulation are improved by arginine. It improves men's erogenous performance [10]. Although it is still in its early stages, modern research on herbal medicine in psychiatry has grown recently, with a 50% rise in the literature in just the five years leading up to 2008 (García-García et al., 2008). Over the last several decades, there has been a proliferation of pre-clinical in vitro and in vivo studies validating many phytotherapy as having a range of bio-psychological effects (Kumar, 2006). These studies have demonstrated beneficial therapeutic activity. Research into psychoactive plants that may affect the Central Nervous System (CNS) has flourished (Spinella, 2001). Many of these "over-the-counter" psychotropic herbal medications are safe and have fewer side effects than traditional pharmacotherapies like antidepressants which can cause sexual dysfunction and other cholinergic symptoms [11].

The herb *Tribulus terrestris* (TT), has been widely used in traditional medicine to energize, vitalize, and enhance men's physical performance and sexual function. The mode of action and efficacy of TT remain unclear and controversial, despite the fact that different effects on men and animals have been evaluated and many active compounds from TT extract have been established [12].

2. Material and methods

2.1. Study Design

An open-label, non-randomized study to clinical validate safety and effectiveness of De-Stress & Perform tablet was conducted on 30 male participants. Each subject received 1 bottle containing 30 De-Stress & Perform Tablet (SSG-3 tablets) for 30 days. Thirty male subjects were recruited at study centre i.e. Lokmanya Medical Research Centre & Hospital, Pune, India. The study was approved by the Institutional Ethics Committee (IEC) Lokmanya Medical Research Centre. The trial was registered on the Clinical Trial Registry of India (CTRI) website (CTRI/2024/03/064117 [Registered on: 14/03/2024]). The composition of the investigational product used in this study, the De-Stress & Perform Tablet, is detailed in Table 1.

Table 1 Investigational product and standard of care product composition

S.N.	Investigational Product	Scientific Name	Quantity
1	Synura® Forte Extract	(Blend of *Mucuna pruriens* ext., *Trigonella feanum-greacum* ext., *Withania somnifera* ext., & L-Arginine)	800.00 mg
2	Saffron Extract	*Crocus sativus*	30.00 mg
3	Gokshura	*Tribulus terrestris*	300.00 mg

2.2. Inclusion criteria

Healthy male individuals aged between 18 to 40 years (both inclusive) were included in the study. A subject experiencing a perceived impact on sexual desire, vitality, stamina, and performance were included. A subject suffering from mild stress on PSS, were in an active stable sexual relationship for the entire duration of the study were included in the study. Subjects who demonstrated their willingness to participate, comply with study procedures by signing a written informed consent and willing for follow up were included in the study.

2.3. Exclusion criteria

Participants who had undergone radical prostatectomy, spinal cord injury, or urogenital surgeries were excluded, as well as those on medications or treatments related to erectile dysfunction (e.g., nitrates, anti-androgens, chemotherapy, radiotherapy) were excluded from the study. Individuals with a history of substance abuse, heavy alcohol use, smoking, neurological conditions, or recent surgeries were also excluded. Those using ayurvedic or dietary supplements for erectile dysfunction in the past three months were not included. Additionally, any participant with a clinical condition deemed unsuitable by the investigator was also excluded.

2.4. Sample Size

Thirty male subjects were planned to enroll in the study based on the clinical and research judgment of the investigators. All subjects received one De-Stress & Perform Tablet daily after a meal for 30 days.

3. Methodology

An open-label, non-randomized study was conducted on 30 individuals. Each subject received 1 bottle containing 30 De-Stress & Perform tablets for 30 days. Thirty male subjects were enrolled and completed the study are depicted in Fig. 1.

During the screening visit, the subject's demographic details were recorded. Medical history and demographic data including sex, age, body weight (kg), and height (cm), habits were recorded during a general screening of subjects which was organized before the study started. Efficacy assessments were done on each visit (baseline and day 30) to assess clinical improvement, vitals, symptoms, and rescue medication. Concomitant diseases & medication assessment was done on screening and baseline. Assessment of changes in CBC, LFT, and RFT parameters was performed on screening and day 30. Assessment of changes in sexual desire using the SDI score at screening and day 30. Assessment of changes in PSS score at screening and day 30. Assessing for changes in self-reported stamina on 4-point Likert scale (0- worsened, 1- not improved, 2- improved, 3- Improved significantly) at screening and day 30. Treatment compliance, safety, and tolerability of the study intervention in terms of adverse events (AEs), and serious adverse events (SAEs) were assessed from baseline to end of the study.

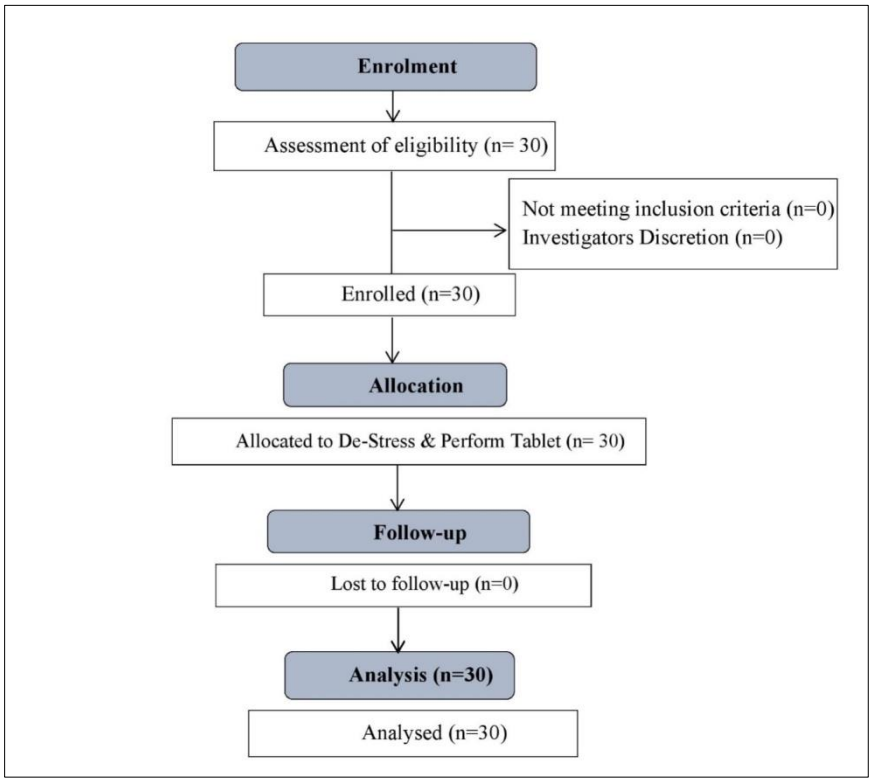

Figure 1 CONSORT flow diagram of the study

3.1. Statistical Analysis

All parameters were checked for normality by 'Kolmogorov-Smirnov Test'. Within group analysis of haematological, biochemical investigations, vital signs, self-reported stamina score, SDI score were done using a dependent student t-test and Wilcoxon signed rank test. In this study, an analysis of demographic details was done using an Independent student t-test. Within group analysis of perceived stress scale score was done using a dependent student t-test. The adverse events were expressed as the number and frequencies of events in groups. Statistical analysis has been done by using Statistical Package for the Social Sciences (SPSS).

4. Results

4.1. Demographic characteristics

All thirty enrolled male participants completed the study. The average age of the subjects was 33.53±4.63 years. Participants had an average weight of 66.93 kg, a height of 165.13 cm, and a BMI of 24.49 kg/m^2. These values fall within clinically acceptable ranges. These demographic details are summarized in Table 2.

Table 2 Demographic Details

Parameter	**Male Mean ± SD (n=30)**
Average Age (Years)	33.53±4.63
Anthropometric Parameters	
Height (cm)	165.13±10.65
Weight (kg)	66.93±11.35
BMI (kg/m^2)	24.49±2.88

Data is represented as Mean ± S.D. Analysis was done using the Independent student t-test. Significant at $p< 0.05$.

4.2. Assessment of hematological and biochemical investigations

There was a statistically significant decrease in the WBC from screening to day 30 ($p = 0.016$). Additionally, the MCHC increased significantly from screening to day 30 ($p = 0.0004$). In the kidney function tests, the mean urea levels increased significantly from screening to day 30 ($p = 0.001$), while the mean creatinine levels decreased significantly from screening to day 30 ($p = 0.001$). The mean uric acid levels also decreased significantly from screening to day 30 ($p = 0.007$). The remaining hematological parameters, including RBC, hemoglobin, hematocrit, MCV, MCH, and platelet count, as well as LFT, did not show any statistically significant changes between screening and day 30. However, all the parameters remained within normal physiological ranges and the changes were not clinically significant (Table 3).

Table 3 Assessment of hematological and biochemical investigations

Blood Parameters				
Parameters	**Screening**	**Day 30**	**P Value**	**Reference Range**
Hematological Parameters				
White Blood Cell Count (WBC)	8166.67±2065.03	7223.33±1703.48	0.016*	(4000 - 11000 cell/cu.mm)
Red Blood Cell Count (RBC)	4.92±0.67	4.69±0.62	0.202	(4.7 - 6.0 mil/cu.mm)
Hemoglobin (Hb)	13.07±2.09	13.60±1.74	0.244	(Male: 13.2-16.6 gm/dL)
Hematocrit (PCV)	40.80±6.12	40.98±5.67	0.906	(42 - 52 %)
Mean Corpuscular Volume (MCV)	82.94±11.95	84.47±9.02	0.351	78 - 100 fL)
Mean Corpuscular Hemoglobin (MCH)	26.70±4.57	27.49±3.71	0.443	(27 - 31 pg)
Mean Corpuscular Hemoglobin Concentration (MCHC)	32.06±1.12	33.11±1.02	0.0004*	(32-36 gm/dL)

Platelet Count	301.50±83.64	297.27±50.04	0.764	(150 - 450 10^3/ul)
Neutrophils	56.03±6.63	58.20±6.17	0.137	(40 - 75 %)
Lymphocytes	35.30±6.19	36.00±4.84	0.513	(20 - 40 %)
Monocytes	4.57±1.61	4.87±1.11	0.378	(2-10 %)
Eosinophils	3.70±0.75	4.00±0.37	1	(1-6 %)
Basophils	0.00±0.00	0.00±0.00	1	(0-1 %)
Liver Function Test				
Protein Total	7.04±0.52	7.09±0.67	0.634	(6.0 - 8.3 g/dL)
Albumin	4.46±0.45	4.49±0.51	0.565	(3.2 - 5.5 g/dL)
Globulin	2.58±0.36	2.59±0.38	0.845	(1.8 - 3.6 g/dL)
A/G Ratio	1.76±0.31	1.76±0.31	0.949	(1.2 - 2.2)
Bilirubin Total	0.62±0.36	0.62±0.32	0.322	(0.1-1.2 mg/dL)
Bilirubin Direct	0.23±0.12	0.24±0.11	0.327	(0-0.4 mg/dL)
Bilirubin	0.39±0.28	0.37±0.27	0.449	Indirect (0.1-0.8 mg/dL)
Aspartate Transaminase (AST/SGOT)	29.85±11.79	29.55±7.64	0.823	(49 U/ L)
Alanine Transaminase (ALT/SGPT)	26.61±9.51	27.30±8.83	0.347	(49 U/ L)
Alkaline Phosphatase	140.06±48.28	139.96±49.36	0.961	(80 - 306 U/ L)
Kidney Function Test				
Urea	20.54±5.44	22.83±5.93	0.001*	(7-40 mg/dL)
Creatinine	0.87±0.24	0.71±0.33	0.001*	(0.5-1.5 mg/dL)
Uric Acid	4.17±0.89	3.96±0.86	0.007*	(3.0 to 7.2 mg/dL)

Data is represented as Mean ± S.D. Analysis was done using the dependent student t-test (within the group) and Wilcoxon signed rank test (within the group). Significant at $p < 0.05$.

4.3. Assessment of vital signs

Respiratory rate showed a statistically significant decrease from screening to day 30 (17.30±1.09 with a p-value of 0.012). However, other vital parameters including systolic blood pressure, diastolic blood pressure, heart rate, and body temperature did not show statistically significant changes from screening to day 30 as demonstrated in **Table 4**. However, all the parameters remained within normal physiological ranges and the changes were not clinically significant.

All thirty subjects were compliant and showed excellent tolerability to the investigational product.

Table 4 Assessment of vital signs

Vitals Parameters			
Parameters	**Screening**	**Day 30**	**P value**
Systolic Blood Pressure (mmHg)	124.00±6.67	121.63±10.73	0.220
Diastolic Blood Pressure (mmHg)	78.17±6.38	77.13±6.57	0.516
Heart Rate (beats per minute)	77.20±6.22	77.90±9.70	0.644
Body Temperature (°F)	97.30±0.92	97.24±0.77	0.735
Respiratory Rate (breaths per minute)	18.27±1.57	17.30±1.09	0.012*

All parameter data (Mean ± SD) was analyzed using the Dependent student t-test and Wilcoxon signed rank test for within the group at p-value < 0.05.

4.4. Assessment of perceived stress using the PSS

The PSS is a ten-question questionnaire with responses from 0 to 4, measuring an individual's stress perception. The total score is the sum of all responses, indicating the perceived stress level. Scores: 0-13 (low stress), 14-26 (moderate stress), 27-40 (high stress).

The assessment of perceived stress using the PSS demonstrated a statistically significant decrease by 61.35% after 30 days of treatment. Data is presented in **Table 5**. The observed change in PSS score was statistically highly significant, suggesting a clinically meaningful improvement in the participant's subjective experience of stress.

Table 5 Assessment of perceived stress using the PSS

Duration	PSS Score (n=30)	P value
Screening	22.07±2.46	<0.001
Day-30	8.53±3.36	

All parameter data (Mean ± SD) was analyzed using the Dependent student t-test and Wilcoxon signed rank test for within the group at p-value < 0.05.

4.5. Assessment of changes in self-reported stamina on 4-point Likert scale

The assessment of changes in self-reported stamina was conducted using a 4-point Likert scale, where 0 represented low stamina; 1 represented good stamina; 2 represented better stamina; and 3 represented highly improved stamina. At screening, there were 10 and 20 participants who reported low and good stamina, respectively. After 30 days of treatment, all participants (100%) shifted to the better-highly improved stamina category **(Table 6)**.

Table 6 Assessment of changes in self-reported stamina on 4-point Likert scale

Assessment of self-reported stamina Number of subjects			
Parameter	**Score**	**Screening (n=30)**	**Day 30 (n=30)**
Stamina	0	10	00
	1	20	00
	2	00	21
	3	00	09

4.6. Assessment of sexual desire using the SDI score

The SDI is a 13-item questionnaire that assesses an individual's level of sexual desire, with scores ranging from 0 (no desire) to 8 (strong desire). The total score is obtained by summing up the scores of all the responses. A higher total score indicates a higher level of sexual desire. The SDI assessment indicated a notable 62.34% increase in self-reported sexual desire score after 30 days of study treatment, showing a statistically significant improvement (**Table 7**).

Table 7 Assessment of sexual desire using the SDI score

Duration	SDI Score (n=30)	P value
Screening	38.13±6.77	< 0.001
Day-30	61.90±6.87	

All parameter data (Mean ± SD) was analyzed using the Dependent student t-test and Wilcoxon signed rank test for within the group at p-value < 0.05.

4.7. Assessment of adverse events and tolerability

The adverse events observed during the study are presented in **Table 8**. Out of the 30 participants, a total of 4 subjects (13.33%) experienced one adverse event each. The reported adverse events were heartburn, fever, vomiting, and headache. AEs observed were mild in nature and were not related to investigational product. All AEs were resolved with appropriate rescue medications. Data is represented in **Table 8**.

All thirty subjects were compliant and showed excellent tolerability to the investigational product.

Table 8 Adverse Events Observed in the Study (N=30)

Adverse Events	**No. of subjects**	**Rescue Medication**
	(N=30)	
Heartburn	1	Omeprazole
Fever	1	Paracetamol
Vomiting	1	Pantoprazole
Headache	1	Aspirin
Total No. of Events	04	
Total No. of subjects (%)	4 (13.33 %)	

5. Discussion

After 30 days of treatment, there were statistically significant reductions in WBC count (p=0.016), creatinine (p=0.001), uric acid levels (p=0.007) and MCHC (p=0.0004). Statistically significant reductions in urea levels (p=0.001) were observed, which was also clinically insignificant. There were no clinically significant changes observed in the vital signs throughout the study. Perceived stress decreased by 61.35% ($p < 0.001$), subject-reported stamina improved, and sexual desire grew by 62.34% ($p < 0.001$). Adverse events (13.33%) were mild and not related to the investigational product. A statistically significant improvement in the participant's subjective sense of stress was suggested by the observed change in PSS score. The treatment group that was given the high-concentration full-spectrum Ashwagandha root extract exhibited a significant reduction These outcomes are consistent with the randomized, double-blind, placebo-controlled trial, where 64 participants with chronic stress received either 300 mg Ashwagandha extract or placebo twice daily for 60 days. The Ashwagandha group showed significant reductions in stress scores and serum cortisol levels compared to placebo. Adverse effects were mild and comparable between groups, confirming the extract's efficacy and safety [13].

The present investigation found a 4-point Likert scale score which evaluated the changes in self-reported stamina Following 30 days of therapy, 100% of the subjects moved into the better/highly improved stamina category. This study's findings align with evidence supporting Ashwagandha and saffron supplementation in improving sexual and overall health. An 8-week trial showed Ashwagandha (300 mg twice daily) significantly increased muscle strength, size, testosterone levels, and reduced body fat compared to placebo, highlighting its role in enhancing physical performance and biomarkers linked to libido and sexual health [14, 15]. Similarly, a systematic review of randomized trials on saffron (*Crocus sativus L.)* found it effective in managing major depressive disorder, premenstrual syndrome, sexual dysfunction, and excessive snacking. Notably, 30 mg/day of saffron improved SSRI-induced sexual dysfunction in men and women with minimal side effects, enhancing arousal, lubrication, and pain [16]. Overall, Ashwagandha and saffron demonstrate potential as safe, natural options for improving sexual health, supporting the findings of this study.

When the study treatment was administered for 30 days, the SDI assessment revealed a statistically significant improvement in the self-reported sexual desire score, with a noteworthy rise of 62.34%. A 4-week randomized, double-blind, placebo-controlled study in 36 men with fluoxetine-induced sexual dysfunction found that 15 mg saffron twice daily significantly improved erectile function and intercourse satisfaction, with 60% achieving normal erectile function. Saffron was well-tolerated, with a safety profile comparable to placebo. These findings align with the present study, supporting saffron's safety and efficacy [17].

The study we conducted demonstrates the WBC count decreased statistically significantly ($p = 0.016$) between screening and day 30. Furthermore, there was a substantial increase in the MCHC between screening and day 30

(p=0.0004). During the renal function tests, there was a substantial increase in mean urea levels (p = 0.001) and a significant decrease in mean creatinine levels (p = 0.001) between screening and day 30. From screening to day 30, the mean uric acid levels also dramatically dropped (p = 0.007). Between screening and day 30, there were no statistically significant changes in the remaining haematological measures, such as RBC, haemoglobin, haematocrit, MCV, MCH, and platelet count, or in the liver function tests. These findings are similar to the findings of the previous trial results on dose-related tolerability, safety, and activity of *Withania somnifera* capsule formulation in apparently healthy volunteers [18].

Previous research highlights the need for improved adverse event reporting in RCTs, with less than half documenting adverse effects, only 16% reporting symptomatic reactions, and just 25% including toxicity biomarkers for major organs. While single herbs or polyherbal formulations are known to improve health outcomes, reliable and generalisable scientific evidence from clinical trials remains limited [19, 20]. In the current study, adverse events were reported by four out of thirty participants (13.33%) and included headache, vomiting, fever, and heartburn. These events were mild and deemed unrelated to the investigational product. This study contributes to the growing body of evidence supporting the product's safety profile, reinforcing its tolerability while addressing the existing gaps in adverse event reporting in clinical trials.

This study's strength lies in its comprehensive evaluation of hematological and biochemical parameters to assess the safety of the De-Stress & Perform Tablet. The trial also examined stress management and sexual performance metrics, demonstrating the tablet's potential therapy for improving overall well-being and addressing stress-related & sexual conditions. The formulation, containing *Mucuna pruriens*, *Tribulus terrestris*, *Withania somnifera*, L-arginine, and saffron, showed significant improvements in stress management and sexual performance, supporting its adaptogenic properties in reducing stress and enhancing physical and mental well-being. However, the study's limitations include a smaller sample size, short duration, and lack of consideration for comorbidities, which future trials should address to strengthen the findings.

6. Conclusion

This study demonstrated that the De-Stress & Perform Tablet is safe and well-tolerated in healthy male subjects, with only four mild adverse events reported, none of which were related to the investigational product. The safety profile, combined with observed improvements in perceived stress, stamina, and sexual desire, supports its potential as a reliable intervention for enhancing overall health. These findings highlight the tablet's safety and suggest its efficacy in promoting well-being, warranting further research to confirm and expand upon these results.

Compliance with ethical standards

Acknowledgments

The authors would like to acknowledge the research team and the back-office team involved in the research work. We would like to acknowledge the support of Mprex Healthcare Pvt. Ltd., Pune, Maharashtra as a clinical research organization for this trial.

Funding

The investigational product was provided by Herbolab India Pvt. Ltd., Mumbai, 400072.

Disclosure of conflict of interest

Dr. Kriti Soni and Dr. Sachin Mulik are part of Herbolab India Pvt. Ltd. Other author declared no conflict of interest.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

References

[1] Drake KV. On the pharmacology of Schizandra chinensis. Farmakol. Toksikol. 1942;5(3236)

[2] Lebedev AA. On the Pharmacology of Schizandra Chinensis. Materials for the Study of Ginseng and Schizandra Chinensis. (3).

[3] Panossian A, Wikman G. Effects of adaptogens on the central nervous system and the molecular mechanisms associated with their stress—protective activity. Pharmaceuticals. 2010 Jan;3(1):188-224.

[4] Kotta S, Ansari SH, Ali J. Exploring scientifically proven herbal aphrodisiacs. Pharmacognosy reviews. 2013 Jan;7(13):1.

[5] Montorsi F, Guazzoni G, Rigatti P, Pozza G. Pharmacological management of erectile dysfunction. Drugs. 1995 Sep; 50:465-79.

[6] Kapoor LD. Handbook of Ayurvedic medicinal plants: Herbal reference library. Routledge; 2017 Nov 13.

[7] Upton R, Graff A, Evans F. Ashwagandha Root: Withania Somnifera: Analytical, Quality Control, and Therapeutic Monograph. Santa Cruz, California: American Herbal Pharmacopoeia. 2000.

[8] Wankhede S, Langade D, Joshi K, Sinha SR, Bhattacharyya S. Examining the effect of Withania somnifera supplementation on muscle strength and recovery: a randomized controlled trial. Journal of the International Society of Sports Nutrition. 2015 Dec; 12:1-1.

[9] Gad MZ. Anti-aging effects of L-arginine. Journal of advanced research. 2010 Jul 1;1(3):169-77.

[10] Zorgniotti AW, Lizza EF. Effect of large doses of the nitric oxide precursor, L-arginine, on erectile dysfunction. International Journal of Impotence Research. 1994 Mar;6(1):33-6.

[11] Sarris J, Panossian A, Schweitzer I, Stough C, Scholey A. Herbal medicine for depression, anxiety and insomnia: a review of psychopharmacology and clinical evidence. European neuropsychopharmacology. 2011 Dec 1;21(12):841-60.

[12] Neychev VK, Mitev VI. The aphrodisiac herb Tribulus terrestris does not influence the androgen production in young men. Journal of ethno pharmacology. 2005 Oct 3;101(1-3):319-23.

[13] Chandrasekhar K, Kapoor J, Anishetty S. A prospective, randomized double-blind, placebo-controlled study of safety and efficacy of a high-concentration full-spectrum extract of Ashwagandha root in reducing stress and anxiety in adults. Indian journal of psychological medicine. 2012 Jul;34(3):255-62.

[14] Wankhede S, Langade D, Joshi K, Sinha SR, Bhattacharyya S. Examining the effect of Withania somnifera supplementation on muscle strength and recovery: a randomized controlled trial. Journal of the International Society of Sports Nutrition. 2015 Dec; 12:1-1.

[15] Shukla KK, Mahdi AA, Mishra V, Rajender S, Sankhwar SN, Patel D, Das M. Withania somnifera improves semen quality by combating oxidative stress and cell death and improving essential metal concentrations. Reproductive Biomedicine Online. 2011 May 1;22(5):421-7.

[16] Hausenblas HA, Heekin K, Mutchie HL, Anton S. A systematic review of randomized controlled trials examining the effectiveness of saffron (Crocus sativus L.) on psychological and behavioral outcomes. Journal of integrative medicine. 2015 Jul 1;13(4):231-40.

[17] Modabbernia A, Sohrabi H, Nasehi AA, Raisi F, Saroukhani S, Jamshidi A, Tabrizi M, Ashrafi M, Akhondzadeh S. Effect of saffron on fluoxetine-induced sexual impairment in men: randomized double-blind placebo-controlled trial. Psychopharmacology. 2012 Oct; 223:381-8.

[18] Raut AA, Rege NN, Tadvi FM, Solanki PV, Kene KR, Shirolkar SG, Pandey SN, Vaidya RA, Vaidya AB. Exploratory study to evaluate tolerability, safety, and activity of Ashwagandha (Withania somnifera) in healthy volunteers. Journal of Ayurveda and integrative medicine. 2012 Jul;3(3):111.

[19] Shepherd A, Brunckhorst O, Ahmed K, Xu Q. Botanicals in health and disease of the testis and male fertility: A scoping review. Phytomedicine. 2022 Nov 1; 106:154398.

[20] Onisei T, Micu AM, Rascol M. Herbal slimming products and natural sexual enhancers. In Aromatic Herbs in Food 2021 Jan 1 (pp. 367-403). Academic Press