Testofen®

Clinical Study for Improvement of Male Sexual Function

Trial Title

A double-blind, randomised, placebo-controlled study to evaluate the effect of an orally-dosed herbal formulation containing *Testofen*, on sexual function and performance in healthy males.

Abbreviated Trial Title

TFN-SFN08

Sponsor Details

AZPA International
17 Concord Drive
Keilor Park VIC 3042

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1.0 Introduction

1.1 Hypothesis

The herbal formulation, when dosed as recommended, improves sexual function, performance and satisfaction in healthy adult males.

1.2 Justification

The Global Study of Sexual Attitude and Behaviours conducted in 27,500 men and women in 30 countries indicates that lack of interest in sex was reported by 18% men and lack of pleasure from sex was by 11%.[1] The benefits of testosterone replacement therapy in men with documented hypogonadism are well recognised, with improved body composition (increased lean body mass, enhanced muscle, diminished visceral fat), mood, cognition, and sexual function.[2,3,4] Basic science studies using a rat model have previously established that the nitric oxide-erectile pathway may be testosterone-dependent and that poor response to sildenafil in men with hypogonadism may be improved with hormone replacement.[5,6]

There has been significant interest in nutritional therapies for sexual function and performance. Some of these therapies have stood the test of time, afforded by their traditional use, while some of these have undergone scientific scrutiny to investigate their evidence for efficacy. However, most of these nutritional supplements have not been tested in rigorous clinical trials. Many trials investigating these supplements have had serious design flaws such as lack of placebo group or effective blinding techniques.

The current study was designed to evaluate the effects of a combination of fenugreek seed extract (*Trigonella foenum-graecum*), magnesium, zinc and vitamin B6.

Efficacy and safety of fenugreek has been established in conditions including diabetes and dyslipidemia by various clinical trials and supported by subsequent reviews.[7,8] Traditional Chinese herbalists used it for kidney problems and conditions affecting the male reproductive tract [9]. It is interesting to note that in Chinese medicine the kidneys are considered to be the area where sexual energy is stored. Fenugreek includes the steroidal saponin diosgenin, choline, trimethylamine (a sex hormone in frogs), Vitamins A, B 2, B 6, B 12, D, and essential oils.[10] Diosgenin is an important precursor for the synthesis of a number of sex hormones, and has been shown to exhibit estrogenic effects.[11]

2.0 Purpose and Objectives

2.1 Primary outcome

Assess the effectiveness of *Testofen* on sexual function, performance and satisfaction.

2.2 Secondary outcomes

Assess effect of *Testofen* on individual parameters of male sexual function (libido);

Assess the effect of *Testofen* on general health, muscle mass, energy, sleep and mood;

Evaluate safety and tolerability of *Testofen*;

Provide information that will be required by Therapeutic Goods Agency (TGA) and international regulatory bodies to support product tolerability and therapeutic claims.

3.0 Methods

3.1 Product

The product is an ARTG listed (AUST-L Number 155497) tablet-form herbal formulation containing:
300 mg TESTOFEN brand Fenugreek Extract Powder
225 mg Magnesium Aspartate equivalent to 16.875 mg Magnesium
78.75 mg Zinc Amino Acid Chelate 20% equivalent to 15 mg Zinc
6.80 mg Vitamin B6 HCL equivalent to 4.94 mg Pyridoxine
Pharmaceutical grade excipients

Dose – 2 tablets / day

3.2 Ethics Approval

The trial was assessed and approved by the Queensland Clinical Trial Network. All communications regarding the trial were with Melissa Hagan (HREC Manager), phone (07) 3331 3999, email: hrec@qctncom.au.

The trial was conducted in compliance with the Declaration of Helsinki, NHMRC National Statement on Ethical Conduct in Research Involving Humans, ICH Guideline for Good Clinical Practice, TGA Note for Guidance on Good Clinical Practice, and the National Privacy Principles and Privacy Act 1988.

3.3 Randomization

The randomisation code is a sequential number (001 to 060) generated by the Random Allocation Software. Enrolled participants were allocated a sequential number from 0001 to 0060 determined by the order (date) in which they are enrolled.

3.4 Participants

The participants were healthy heterosexual males aged between 21-50 years of age.

3.5 Recruitment

Participants were recruited from the CRO's subject database and public media outlets.

3.6 Inclusion and Exclusion Criteria

The trial was conducted on healthy males interested in increasing libido. These men did not have sexual dysfunction and in a stable sexual relationship. The Inclusion and Exclusion Criteria are listed in Appendix A.

3.7 Enrolment and Data Collection

Following preliminary screening via telephone/email of information forms, participants attended the clinic for an information session and to enrol in the trial.

The consenting potential subjects completed the consent forms, filled out appropriate background information (including lifestyle, current medications and medical history). The participants also completed all questionnaires. Participants were provided with the pathology slip and instructions for the blood collection. Blood collection and serum analysis was carried out by QML laboratories, Central Laboratory 11 Riverview Place Metroplex on Gateway Murarrie, QLD 4172.

At the subsequent data collection points (weeks 3 and 6), the participants were assessed for any changes to lifestyle and health / medical status (via phone) and completed the questionnaires.

Within the seven days prior to due completion of the trial, participants had blood collected for post-trial analysis (through the QML laboratories). At completion of the trial, a trial-exit interview was conducted to collect final data and assess the participant's health and wellbeing.

3.8 Completion and withdrawals

Initially, 60 participants were enrolled in the trial. There were 6 withdrawals from the study (3 from the Active group and 3 from the Placebo group) so the analysis was completed on the remaining 54 participants.

4.0 Outcome Measures and Results

4.1 Primary Outcome Measure

Effect of *Testofen* on sexual function, performance, and satisfaction (libido).

To determine the effectiveness of *Testofen* on sexual function, performance, and satisfaction, the validated quantitative Derogatis Interview for Sexual Functioning (DISF-SR) (Male) was used. The DISF-SR consists of a total of 21 questions divided into 4 domains that ask about different aspects of sexual experiences: sexual fantasies, kinds of sexual arousal, nature of sexual experiences and quality of orgasm. See Appendix D for the DISF-SR.

The DISF/DISF-SR is designed to be interpreted at three distinct levels: the discrete item level (e.g., "A full erection upon awakening", "Your ability to have an orgasm"), the functional domain level (e.g., Sexual Arousal Score), and the global summary level (e.g., DISF/DISF-SR Total Score).

On some questions participants were asked to respond in terms of a frequency scale, that is "how often" in terms of particular sexual activities. Some frequency scales range from "0 = not at all" to "8 = four or more times per day". Other frequency scales range from "0 = never" to "4 = always". With other questions, they were asked to respond in terms of a satisfaction scale. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better". Other satisfaction scales range from "0 = not all satisfied" to "4 = extremely satisfied".

Participants completed the CRF for this data pre-trial (baseline data), and upon completion of weeks 3 and 6.

Results:

The DISF-SR questionnaire is designed in such a way that participants record higher scores when they feel a greater satisfied with a particular area. The results are summarized in Table 1 and Figure 1.

The highest total score possible for the DISF-SR is 144 points. There was no statistical difference between the average total DISF-SR score for the Active group (n=27) and the Placebo group (n=27) at baseline; (67.59 and 72.93 respectively).

There was a significant increase in total average score in the Active group, compared to baseline (67.59 to 75.67, $p = 0.017$) after 3 weeks. A further increase in total average score was observed at 6 weeks indicating continued improvement (82.48, $p = <0.001$).

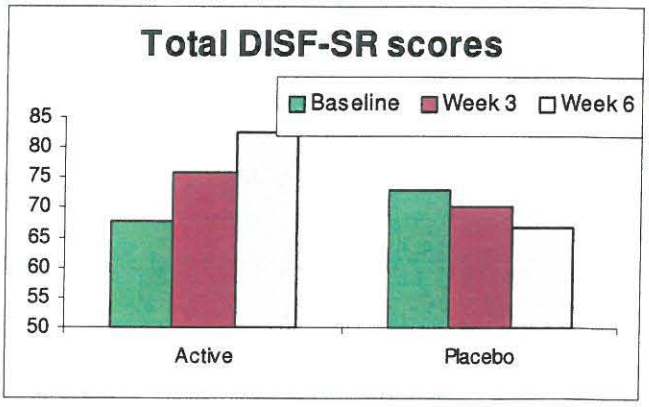
There was no increase observed in the total average score for the Placebo group. There was a slight decrease at 3 weeks (72.93 to 70.25) and it continued to decrease below baseline at week 6 (to 66.81).

The inter-group difference between active and placebo was calculated at week 3 and week 6. A statistically significant inter-group difference was found at week 6 (p=0.004). This supports our hypothesis that Testofen improves libido in healthy adult males.

Table 1: DISF-SR Total scores in the Active and Placebo groups at Baseline, 3 and 6 weeks

	Active Group (n=27)	**Placebo Group (n=27)**	**Difference between groups**
	Total Scores	Total Scores	P values
Baseline	67.59	72.93	p = 0.309
Week 3	75.67 (p = 0.017) significant difference compared to baseline	70.25	p = 0.156
Week 6	82.48 (p <0.001) significant difference compared to baseline	66.81	p = 0.004

Figure 1: DISF-SR Total scores in the Active and Placebo groups at Baseline, 3 and 6 weeks



Summary:

These results suggest that *Testofen* has a positive effect on sexual function, performance, and satisfaction (libido).

4.2 Secondary Outcome Measures

The effect of *Testofen* on Individual parameters of male sexual function (libido)

The individual parameters of male sexual function (libido) were assessed by the validated quantitative DISF-SR (Male) domain sub-scores. The results are summarized in Table 2 and Figure 2.

Table 2:
DISF-SR domain sub-scores in the Active and Placebo groups at Baseline, 3 and 6 weeks

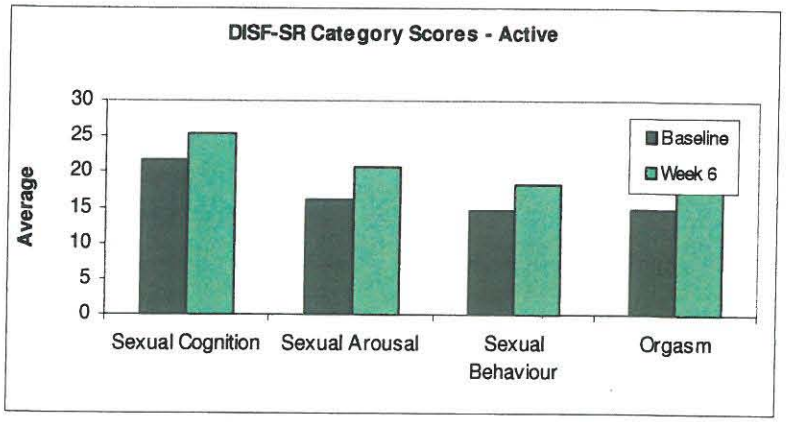
Domains	Active Group (n=27)	Placebo Group (n=27)
1. Sexual cognition		
Baseline	21.78	23.96
Week 3	23.48	23.28
Week 6	25.36	21.68
Total possible score 40		
2. Sexual arousal		
Baseline	16.07	17.81
Week 3	18.70	18.16
Week 6	20.56	16.56
Total possible score 40		
3. Sexual behaviour		
Baseline	14.69	15.96
Week 3	17.29	14.53
Week 6	18.32	14.28
Total possible score 40		
4. Orgasm		
Baseline	14.78	15.18
Week 3	16.19	14.28
Week 6	18.24	14.29
Total possible score 24		

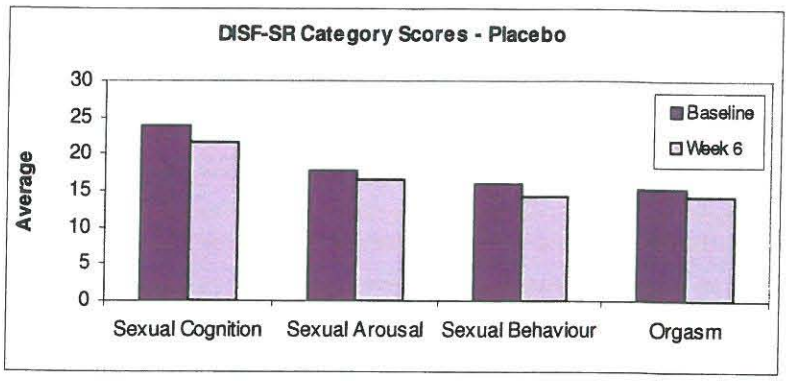
Table 3:
Statistical analysis of active vs baseline, placebo vs baseline and inter-group difference active vs placebo (p values)

	Active vs Baseline		Placebo vs Baseline		Active vs Placebo	
	Week 3	Week 6	Week 3	Week 6	Week 3	Week 6
Total DISF-SR	0.017*	0.00007*	0.053	0.007**	0.157	0.004***
Sexual Cognition	0.124	0.002*	0.065	0.005**	0.517	0.129
Sexual Arousal	0.004*	0.00004*	0.183	0.021**	0.430	0.057
Sexual Behaviour	0.006*	0.0006*	0.002**	0.002**	0.043***	0.013***
Orgasm	0.017*	0.00001*	0.028**	0.082	0.079	0.002***

Note there was no difference between the placebo and active group at baseline (p=0.309)
*statistically significant difference (Positive) when compared to baseline
**statistically significant difference (Negative) when compared to baseline
*** statistically different inter-group difference active vs placebo

Figure 2:
DISF-SR domain sub-scores in the Active and Placebo groups at Baseline, 3 and 6 weeks





Domain 1 - Sexual cognition/fantasy:

This domain consisted of 5 questions with total possible score of 40.

There was an increase in Sexual Cognition in the Active group by week 3 (average domain score of 21.78 to 23.48). This positive trend continued and there was a significant increase by week 6, with an average domain score of 25.36, $p = 0.002$). In contrast, there was no improvement observed in the Placebo group, rather a decrease was observed.
No significant inter-group difference was found between the active and placebo treatments at week 3 or 6.

Domain 2 - Sexual Arousal:

This domain was characterised by 5 questions with a total score of 40.

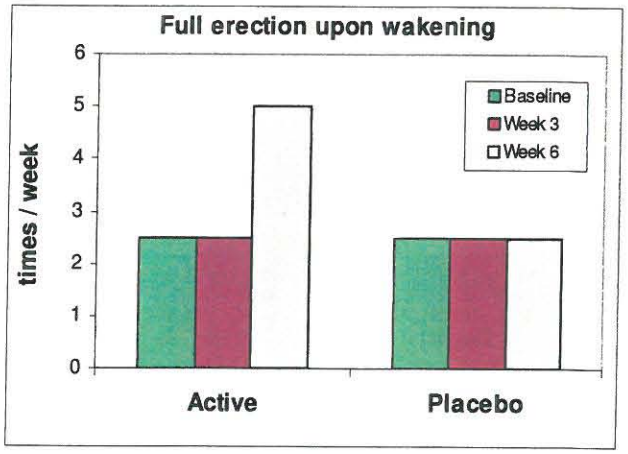
There was a significant increase in the Sexual Cognition domain in the Active group compared to baseline, with an initial increase observed at 3 weeks (16.07 to 18.7, p = 0.005) and then a further increase (to 20.56, p <0.001) by week 6. There was a slight negative change in the average total score in Placebo group at week 3 and a significant decrease by week 6.
No significant inter-group difference was found between the active and placebo treatments at week 3 or 6.

Individual questions

Q 2.1 A full erection upon awakening

All participants had reported that a full erection upon awaking only occurred 2 to 3 times a week at baseline. However, after treatment, the Active reported an increase to 5 to 6 times a week, while no change was recorded in the Placebo group (see Figure 3).

Figure 3:
DISF-SR Question 2.1 in the Active and Placebo groups at Baseline and 6 weeks



Q 2.5 A full erection throughout the phases of a normal sexual response cycle.
(from undressing and foreplay, through intercourse and orgasm)

All participants had reported a frequency 1 times a week at baseline. However, the Active group had reported an increase to 2 to 3 times a week, while no change was recorded in the Placebo group.

Domain 3 - Sexual Behaviour:

This domain assesses aspects of Sexual Behaviour, using 5 questions with a total possible score of 40. The average score in the Sexual Behaviour domain for the Active group increased significantly by week 3 compared to baseline (from 14.69 to 17.29). This trend continued with a further increase at week 6 (to 18.32, p <001). There was a significant decrease in the Placebo group.

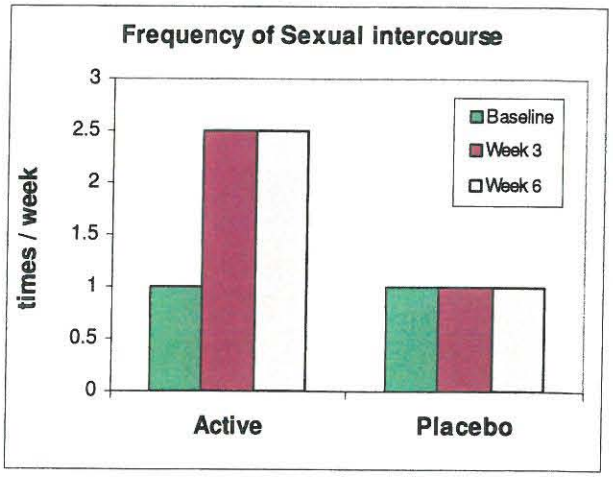
A significant inter-group difference was found between the active and placebo treatments at both week 3 and 6, supporting the hypothesis that Testofen improves sexual behaviour / function in healthy adult males.

Individual Questions

Q 3.5 Frequency of Sexual intercourse

Within this domain, the question regarding frequency of sexual intercourse was asked. All participants had reported a frequency 1 episode per week at baseline. However, the Active group had reported an increase to 2 to 3 times a week, while no change was recorded in the Placebo group (see Figure 4).

Figure 4: Frequency of sexual activity at Baseline and at week 6.



Domain 4 - Orgasm:

This domain focuses on aspects of satisfaction with Orgasm, using 6 questions with total score of 24.

The average domain score in the Orgasm domain for the Active group increased within the first 3 weeks (from 14.78 to 16.19). This trend increased and by week 6 a significant increase compared to baseline was observed (18.24, $p < 0.001$). The Placebo group recorded a decrease in the total domain score by week 6 however this was not significant.

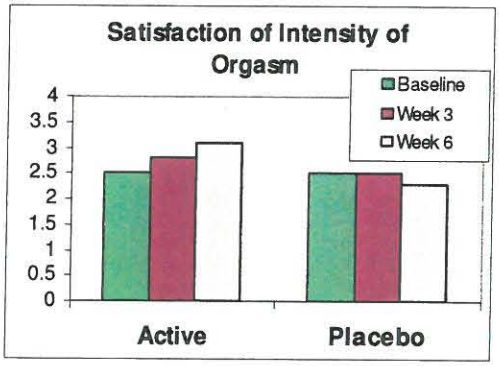
A significant inter-group difference was found between the active and placebo treatments at week 6, supporting the hypothesis that Testofen improves satisfaction and intensity of orgasm in healthy adult males.

Individual questions

Q 4.2 Satisfaction with intensity of your orgasm

On a 1 to 4 scale the satisfaction increased from 2.5 (moderately satisfied) to 3.1 (highly satisfied) in the Active group. There was no change observed in the Placebo group (Figure 5).

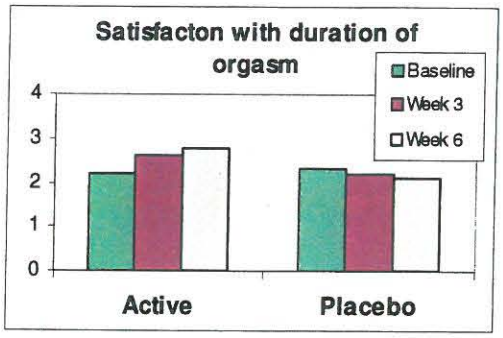
Figure 5:
DISF-SR Question 4.2 in the Active and Placebo groups at Baseline and 6 weeks



Q 4.3 Satisfaction with the length of duration of your orgasm

On a 1 to 4 scale the satisfaction increased from 2.2 (moderately satisfied) to 2.8 (highly satisfied) in the Active group. There was no change observed in the Placebo group (Figure 6).

Figure 6:
DISF-SR Question 4.3 in the Active and Placebo groups at Baseline and 6 weeks



Summary:

In summary, *Testofen* showed a significant increase when compared to baseline in all domains of the DISF-SR sexual cognition (interest), increases sexual arousal, increases sexual activity and orgasm itself.
Significant inter-group differences were found at week 6 for the domains, sexual behaviour and orgasm.

The effect of *Testofen* on Libido, muscle mass, strength, energy, stamina and sleep

To determine the effect of *Testofen* on other associated parameters of male health, a 10 point scale rating of satisfaction was completed pre-trial (baseline) and at 6 weeks. It was also used to cross-check the information provided in the DISF-SR. See Appendix B for the QOL2. The results are summarized in Table 3 and Figure 4.

Libido

In the Active group, 85.2% (23 of 27) reported a higher rating in the areas of Libido after completing the trial. This was a significant positive increase (change of 4.9 to 7.4, $p<0.001$), in line with the results in the DISF-SR. There were 77.8% of participants(21 of 27) reporting a higher rating in Performance, with an average increase from 5.6 to 7.3 ($p<0.001$). There was no change observed in the Placebo group.

Muscle and Strength

There were also higher ratings in muscle mass with 63.0% (17 of 27) reporting greater satisfaction with muscle (6.0 to 6.9, $p<0.001$). This was also accompanied by higher ratings in strength in 66.7% (18 of 27) with an average change of 6.1 to 7.1 ($p<0.001$). There was no change observed in the Placebo group in either muscle mass or strength.

Energy, Stamina and Sleep

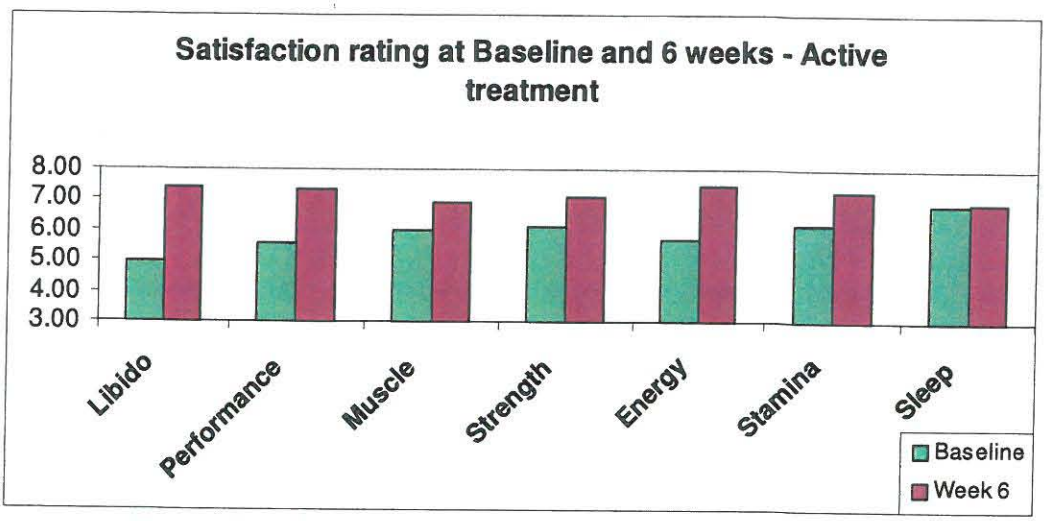
In the Active group, 77.8% (21 of 27) also reported a higher rating in energy levels. The average change was (5.7 to 7.5, $p<0.001$). There was less noticeable changes in the area of stamina, with 51.2% (13 of 27) reporting a higher rating, with the average change of 6.1 to 7.3, $p<0.001$). There was no change observed in the Placebo group in these parameters.

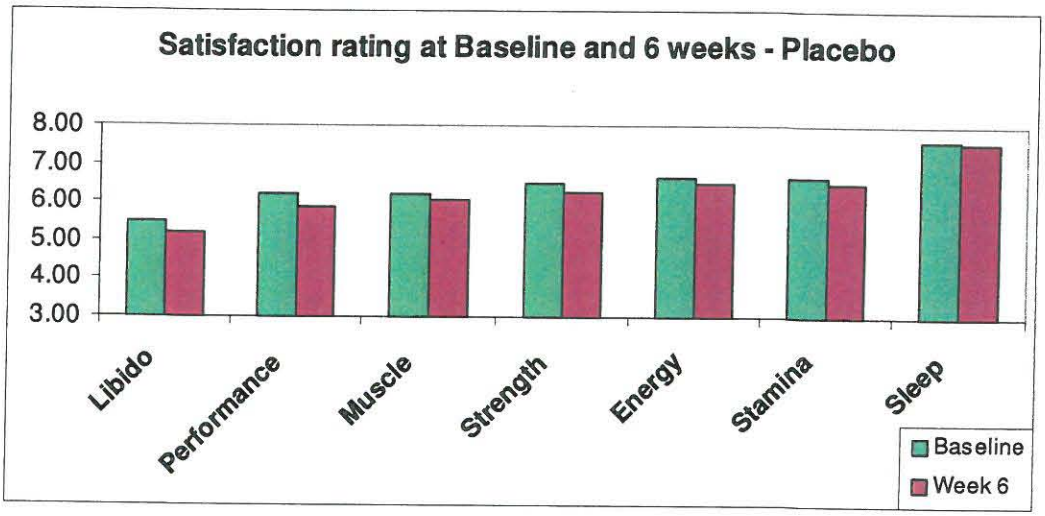
Interestingly, only 29.6% (9 of 27) reported a higher rating for sleep although, overall, the average rating remained the same. It should be noted, that, on average, there was a generally high level of satisfaction with the quality of sleep in this study group.

Table 4: Effects of *Testofen* on Libido, muscle mass, strength, energy, stamina and sleep in Active and Placebo groups at Baseline and 6 weeks

	Active Group (n=27)	Placebo Group (n=27)
Libido		
Baseline	4.9	5.5
Week 6	7.4 ($p < 0.001$)	5.2
Improvement	**23 (85.2%)**	
Performance		
Baseline	5.6	6.2
Week 6	7.3 ($p < 0.001$)	5.9
Improvement	**21 (77.8%)**	
Muscle		
Baseline	6.0	6.2
Week 6	6.9 ($p < 0.001$)	6.1
Improvement	**17 (63.0%)**	
Strength		
Baseline	6.1	6.5
Week 6	7.1 ($p < 0.001$)	6.2
Improvement	**18 (66.7%)**	
Energy		
Baseline	5.7	6.6
Week 6	7.5 ($p < 0.001$)	6.5
Improvement	**21 (77.8%)**	
Stamina		
Baseline	6.1	6.6
Week 6	7.3 ($p < 0.001$)	6.5
Improvement	**14 (51.2%)**	
Sleep		
Baseline	6.9	7.6
Week 6	6.9	7.6
Improvement	**8 (29.6%)**	

Figure 4: Effects of *Testofen* on Libido, muscle, strength, energy, stamina and sleep in Active and Placebo groups at Baseline and 6 weeks.





Summary:

Overall, these results suggest that *Testofen* exerts a positive effect on muscle, strength and energy levels.

Quality of Life Survey

At the completion of the trial, participants also completed a subjective Quality of Life Survey (QOL3).

This is useful information, as it provides more clinical outcome rather than just the statistical significance as assessed in the other questionnaires. See Appendix C for the QOL3.

These results indicate that majority of Active group felt improvements in libido (81.5%; 22 of 27), recovery time (66.7%; 18 of 27%) and quality of sexual performance (63.0%; 17 of 27) as a result of taking the product.

In additional, the majority of Active group also felt there was improvement in general energy (81.5%; 22 of 27) and wellbeing (55.6%; 15 of 27). Overall, there was very little change in mood and sleep. These results correlate with the findings in the DISF-SR and the QOL2.

On average, the Active group believed there was an improvement in libido, recovery and quality of sexual performance as well as general energy and wellbeing. In contract, there was no change in all domains in the Placebo group. The results are summarized in Table 5.

Table 5: Averaged Reported quality of Life in Active and Placebo at Baseline and 6 weeks (1-5 scale).

	Active Group (n=27)	Placebo Group (n=27)
Libido	3.48	2.07
Recovery time after sexual activity	3.19	2.04
Quality of sexual performance	3.07	2.00
General energy level	3.33	2.07
General wellbeing	2.96	2.03
Sleep	2.37	2.03
Mood	2.56	2.07

How would you rate the effect of the product on the following?
1. Worse than before taking product, 2. No change, 3. Slight improvement, 4. Moderate improvement, 5. Significant improvement

Summary:

These results are consistent with the DISF-SR and the QOL2 questionnaires, indicating that *Testofen* has a positive effect on sexual function, energy and wellbeing.

4.3 Pathology Results

Screening tests - FBC and PSA levels

Participants had Full Blood Count (FBC) and Prostate Specific Antigen (PSA) tests at baseline. The FBC collected data on general blood chemistry, including serum iron levels and white blood cell levels (immune function). The PSA is a marker for non-specific inflammation of the Prostate. The results were within normal reference range for all participants.

Safety Testing

Prolactin levels

At baseline, all participants had prolactin levels within the normal reference range of < 15 nmol/L), Active group (5.8 nmol/L) and Placebo group (6.1 nmol/L) at baseline.

These levels remained in the normal reference range for both the active and placebo group at week 6.

Serum testosterone levels

All participants had total testosterone levels within the normal healthy reference range (10-33 nmol/L). The average total testosterone: Active group; 14.8 nmol/L, Placebo, 14.3 nmol/L.

The total testosterone levels remained within normal reference range after treatment in both the Active group and Placebo group. This confers with other studies that Fenugreek is safe to use, and while it has androgenic properties, will not push testosterone levels to an unhealthy high level in men who have a normal testosterone output. It should be noted that these men were fairly sedentary and none were actively involved in serious sporting activities, body building or weightlifting.

There are many factors that can influence hormonal status in men as well as the treatment, including age, body weight (in particular fat mass) and relationship status. However, there was no correlation between the following parameters at baseline:

1. Age and testosterone levels
2. Age and prolactin levels
3. Body weight and testosterone levels
4. Body weight and prolactin levels

Safety Data and Adverse Effects

There were no adverse events recorded during the trial. The product was well tolerated. It was noted that a few participants felt that it may have caused slight stomach upsets when taken on an empty stomach.

5.0 Discussion

The 4 domains of the DISF-SR represent the emotional/ mental aspects of libido (Sexual cognition and sexual arousal) and the physical aspects of libido (Sexual behaviour and orgasm). By week 3 both the active and placebo groups were showing trends and slight increases in the emotional / mental aspects of libido. This was expected as the participants as a result of being in the study, were more focussed on libido and sex. It is interesting to note that although both groups were thinking about sexual experiences more, only the active group showed any significant increase in the physical aspects of libido. This indicates that the product was having the physiological effect needed to act out the mental / emotional desire. The inter-group analysis also supports this theory as there were no differences between the active and placebo group for the emotional domains, however there was a significant difference between the two groups for the physical domains and overall score by week 6.

Another unusual outcome of this study was the significant reduction in DISF-SR score in the placebo group. Although the reason for this is unknown, one possible explanation is that when those in the placebo group were experiencing more sexual thoughts, they were not feeling any physical differences, and therefore became disappointed and uninterested.

Overall the results indicated that Testofen was having a physiological effect on libido, sexual function and performance as well as recovery, muscle, energy levels and general wellbeing. The likely mechanism of action is androgenic, with the product exerting some subtle effect on the steroid hormone pathway. However, due to the changes in energy and stamina it is also possible that the product is also having a metabolic effect. Further studies will be needed to ascertain the exact mechanisms of action.

6.0 Conclusions

This study has provided the following information:

Testofen has an overall positive effect on sexual function, performance, and satisfaction (libido) in healthy adult males.

Testofen has a positive effect, on sexual cognition, sexual arousal increases sexual activity and satisfaction with orgasm in healthy adult males.

Testofen has a positive effect on frequency of sexual activity.

Testofen has a positive effect on muscle, strength, energy and wellbeing in healthy adult males.

Testofen does not have an effect on mood and sleep in healthy adult males.

Prolactin levels and Testosterone levels remained within healthy reference range after 6 weeks of treatment demonstrating that *Testofen* is safe to use in healthy men to support libido function.

Testofen may help to maintain healthy testosterone levels.

Testofen was well tolerated and has no adverse effects when taken as directed over 6 weeks.

Overall, these results indicate that Testofen is a safe and effective product for improving libido in healthy adult males.

26th November 2009

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Investigator, Director Applied Science and Nutrition

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Appendix A: Inclusion and Exclusion Criteria

Inclusion Criteria

Inclusion Criteria

- Heterosexual male aged between 25-50
- Stable sexual relationship for at least the last 6 months
- Sexually active for at least the last 6 months
- Anticipated stable sexual relationship for at least the next 8 weeks
- Sexual partner willing to provide information during interviews
- Written informed consent from the subject

Exclusion Criteria

Subjects will be excluded for any one of the following reasons:

- Homosexual orientation
- Any condition which in the opinion of the investigator makes the subject unsuitable for inclusion
- Known hypersensitivity to herbal drugs/nutritional supplement/ foods
- Possible physical unavailability of sexual partner during trial period
- Any physical disability that may limit sexual function
- Received any treatment/therapy for any sexual disorder during last 6 months
- Receiving/ prescribed coumandin (Warfarin), heparin, daltaparin, enoxaparin or other anticoagulation therapy
- Receiving/ prescribed levodopa (Sinemet) for Parkinson's Disease or calcipotriene (Dovonex) for Psoriasis
- Diagnosed with hypertension and receiving/ prescribed antihypertensive medications
- Diagnosed severe renal and/or hepatic insufficiency
- Diagnosed genital anatomical deformities, uncontrolled diabetes mellitus, and history of spinal cord injury, uncontrolled psychiatric disorder, and/or abnormal secondary sexual characteristics
- Diagnosed prostatic cancer or benign hypertrophy; if suspected by the investigator, refer for medical assessment
- Acute genitourinary disorder
- History of genital surgery
- Current or history of chronic alcohol and/or drug abuse
- Suspected or diagnosed chickpea allergy
- Participation in any other clinical trial during last 30 days
- Simultaneous participation in another clinical trial

Appendix B: QOL2

On a scale of 1-10 (1 = not satisfied, 10 = extremely satisfied) how would you currently rate the following;

Libido	1 2 3 4 5 6 7 8 9 10
Sexual performance	1 2 3 4 5 6 7 8 9 10
Muscle mass	1 2 3 4 5 6 7 8 9 10
Strength	1 2 3 4 5 6 7 8 9 10
Energy	1 2 3 4 5 6 7 8 9 10
Stamina	1 2 3 4 5 6 7 8 9 10
Sleep	1 2 3 4 5 6 7 8 9 10

Appendix C: Quality of Life Questionnaire

How would you rate the effect of the product on the following?

1. Worse than before taking product,

2. No change,

3. Slight improvement,

4. Moderate improvement,

5. Significant improvement.

Libido	1 2 3 4 5
Recovery time after sexual activity	1 2 3 4 5
Quality of sexual performance	1 2 3 4 5
General energy level	1 2 3 4 5
General wellbeing	1 2 3 4 5
Sleep	1 2 3 4 5
Mood	1 2 3 4 5

Appendix D: DISF-SR

Below you will find a brief set of questions about your sexual activities. These questions are divided into sections that ask about different aspects of your sexual experiences. One section asks about sexual fantasies or daydreams, while another enquires about the kinds of sexual experiences that you have. You are also asked about the nature of your sexual arousal and the quality of your orgasm. There are also a few other questions about different areas of your sexual relationships.

On some questions you are asked to respond in terms of a frequency scale, that is "how often" do you perform the sexual activities asked about in that section. Some frequency scales range from "0 = not at all" to "8 = four or more times per day". Other frequency scales range from "0 = never" to "4 = always". With other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied, by the sexual activating being asked about. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better". Other satisfaction scales range from "0 = not all satisfied" to "4 = extremely satisfied".

In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. For each item, please circle the scale number that best describes you personal experience. If you have any questions, please contact the investigator who gave you the inventory for help.

Section 1: Sexual Cognition / Fantasy

During the past two weeks, how often have you had thoughts, dreams, or fantasies about:

8	= 4 or more per day	3	= 1 per week
7	= 2 or 3 per day	2	= 1 or 2 per month
6	= 1 per day	1	= less than one per month
5	= 4 to 6 per week	0	= not at all
4	= 2 or 3 per week		

1.1	A sexually attractive person	0	1	2	3	4	5	6	7	8
1.2	Erotic parts of a woman's body (e.g. face , genitals, legs)	0	1	2	3	4	5	6	7	8
1.3	Erotic or romance situations	0	1	2	3	4	5	6	7	8
1.4	Caressing, touching, undressing, or foreplay	0	1	2	3	4	5	6	7	8
1.5	Sexual intercourse, oral sex, touching to orgasm	0	1	2	3	4	5	6	7	8

Sub-score: (office use only) ☐

Section 2: Sexual Arousal

During the past two weeks, how often did you have the following experience:

8	= 4 or more per day	3	= 1 per week
7	= 2 or 3 per day	2	= 1 or 2 per month
6	= 1 per day	1	= less than one per month
5	= 4 to 6 per week	0	= not at all
4	= 2 or 3 per week		

2.1	A full erection upon awakening	0	1	2	3	4	5	6	7	8
2.2	A full erection during a sexual fantasy of daydream	0	1	2	3	4	5	6	7	8
2.3	A full erection while looking at a sexually arousing person, movie, or picture	0	1	2	3	4	5	6	7	8
2.4	A full erection during masturbation	0	1	2	3	4	5	6	7	8
2.5	A full erection throughout the phases of a normal sexual response cycle. That is, from undressing and foreplay , through intercourse and orgasm	0	1	2	3	4	5	6	7	8

Sub-score: (office use only) ☐

Section 3: Sexual Behaviour / Experiences

During the past two weeks, how often did you engage in the following sexual activities:

8	= 4 or more per day	3	= 1 per week
7	= 2 or 3 per day	2	= 1 or 2 per month
6	= 1 per day	1	= less than one per month
5	= 4 to 6 per week	0	= not at all
4	= 2 or 3 per week		

3.1	Reading or viewing romantic or erotic books and stories	0	1	2	3	4	5	6	7	8
3.2	Masturbation	0	1	2	3	4	5	6	7	8
3.3	Casual kissing or affectionate play	0	1	2	3	4	5	6	7	8
3.4	Sexual foreplay	0	1	2	3	4	5	6	7	8
3.5	Sexual intercourse, oral sex, etc.	0	1	2	3	4	5	6	7	8

Sub-score: (office use only) ☐

Section 4: Orgasm

During the past two weeks, how satisfied have you been with the following:

4	= Extremely
3	= Highly
2	= Moderately
1	= Slightly
0	= Not at all

4.1	Your ability to have an orgasm	0	1	2	3	4
4.2	The intensity of your orgasm	0	1	2	3	4
4.3	The length of duration of your orgasm	0	1	2	3	4
4.4	The amount of seminal fluid you ejaculate	0	1	2	3	4
4.5	Your sense of control (timing) of your orgasm	0	1	2	3	4
4.6	Feeling a sense of relaxation and well-being after orgasm	0	1	2	3	4

Sub-score: (office use only) ☐

Total score: (office use only) ☐