

Clinical Nutrition





Study on Sexual Desire

Sexual Desire in Men: Effects of Oral Ingestion of a Product Derived from Fertilized Eggs

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KEY WORDS	SUMMARY
Libido	A Commercial product, Libido® (Libid, Libbido, Erosom and Ardorare, names used in different markets), which based on components derived from fertilized, partly
Ardor	incubated chickens' eggs, has been used to treat diminished sexual desire in men. The results from two double-blind cross-over placebo-controlled experiments indicate that Libido has a significant enhancing effect on sexual desire in men with normal and
Erosom	reduced sexual drive. Over periods as short as 2 weeks, 58% of the participants with low sexual desire noticed improvement as assessed using a visual analogue scale. Data
Aphrodisiac	obtained from consumers suggest significant effects on the frequency of sexual intercourse, on increased self-esteem, on the level of happiness, and on stamina. In a separate Swedish study, 84% of 31 men reported increased sexual desire during 3
Egg Product	weeks on Libido. It takes 1-2 weeks of regular use of Libido (3g twice daily) before noticeable changes are observed.
Sexual Desire	

INTRODUCTION

Through the ages people have searched for substances and dietary supplements that affect sexual drive or desire. A number of remedies have been developed and tried. For instance the rhinoceros population has been at the edge of extension because of the belief that rhinoceros horn is an effective aphrodisiac. Many of the early aphrodisiacs derived their reputation from physical qualities such as resemblance to genitalia (e.g. rhinoceros horn, ginseng root, cucumbers).

Over the years, hundreds of so-called aphrodisiacs have been tried and investigated; some have gained reputations for having real effects on sex drive, but the studies done lacked a placebo-treated group. The authors are of the opinion that the placebo effect may be considerable in this type of study, and may account for as much as 50% of the apparent effect.

Reduced sex drive is a complex problem; by nature, sexual desire and performance decline with age. Sex drive can also be effected by disease and drug treatment. It is unreasonable, therefore, to expect that

an individual remedy will have a good effect on all those with reduced sex drive.

As people nowadays are more aware of and open about their sexual feelings, it is clear that reduced sex drive and performance is a larger problem than previously anticipated. In a study of sexual problems carried out by the Norwegian Association for Sexology, 13% of men and 38% of women indicated that their main problem was lack of sex drive. Men may not be as honest as women when answering questionnaires about their sexuality, so the figures for men may, in reality, be similar to those for women. Rosselini estimated that approximately 38 of the 150 million American adults have no desire for sex. Since a relatively large part of the population is suffering diminished sex drive, a product that effectively increases sex drive would be valuable. The rationale for using components derived from fertilized chickens' eggs incubated to a pre-embryonic stage, as enhancers of sexual desire, is based on the assumption that these components are transformed into active substances body, e.g. stimulating

steroidogenesis and/or acting as sex hormone precursors. Other possible mechanisms include a neutrophil effect, and stunting effects on the cholesterol derivatives, stimulating production of sex hormones instead of cortisol, as the precursors are identical. The main ingredient in the product, Libido® used in the present studies is derived from chickens' eggs.

The purpose of this study was to investigate in placebo-controlled studies whether the product Libido® is effective in enhancing the sex drive of men.

SUBJECTS AND METHODS

The product, Libido®, is derived from partly incubated fertile chickens' eggs and protein fractions extracted, lyophilized and made into a powder.

This is main constituent of Libido® (> 80%). To make the product more acceptable and complete from a sensory and nutritional point of view, some plant ingredients, vitamins and minerals were added. Doseresponse studies were not available when our studies began. The daily dose was decided on the basis of preliminary empirical data collected from samples distributed among friends and volunteers, which showed that 5 - 6 g daily produced an appreciable effect. In our studies the dose was therefore set at 3g twice (morning and evening). investigational products (Libido®/placebo) for the two double-blind studies were packed in identical sachets containing 3g, and labeled with the instruction that two sachets should be taken every day, one in the morning, and one in the evening. The product was to be dissolved in 200 ml of liquid (juice or water), stirred and swallowed immediately. The taste, appearance and solubility of the two products were identical.

Study 1

This study was initiated to investigate the effect of Libido® on sex drive, compared with placebo, in a group of middle-aged men. This was a randomized placebo-controlled double-blind study with a duration of 6 weeks. (i.e., 3 weeks on each of the two preparations).

Only healthy middle-aged men (47 – 60 years) were included in the study. Patients receiving drug therapy were excluded.

The subjects required for this study came from a local rotary club.

Volunteers were given written and verbal information about the aims of the study, and gave written consent. As the study involved only healthy volunteers, using an approved nutritional product, it was not considered necessary to obtain Ethics Committee approval.

The participants came once a week to the research institute conducting the study, to report their scores and any adverse events that could possibly be linked to the treatment. Compliance with the treatment schedule was also checked at each visit; volunteers were required to have taken at least 80% of the recommended dose of the powder to be included in the evaluation of the effect.

Sixteen men aged 47 – 60 years (average 52.5 years) participated in the study. Half of the participants received Libido® during the first period of three weeks, and the rest received placebo. In the second part of the study, the treatments were reversed. There was no wash-out period between the two treatments. The patients scored their feeling of sexual desire on a weekly basis, using a visual analogue scale ranging from 0 cm, no change, to 10 cm, very pronounced change. This was the only efficacy parameter used. The statistical comparisons were made using Student's t-test with a significance level of 5%.

Based on the positive results from this placebocontrolled cross-over pilot study, the decision was taken to carry out a further placebo-controlled study in a larger male population.

Study 2

The volunteers for this study were acquired through an advertisement in a local newspaper, in which the aim of the study was presented. The responders were asked to the clinic for an interview and a clinical examination. The study was approved by the clinic's Ethics Committee.

Only healthy men with reduced sexual desire not caused by organic changes, mental impairment or drug intake were included. Patients were excluded if the reduced sexual desire was of chronic and/or mental origin, or if they were receiving drug therapy. The clinic is a specialized clinic for people with sexual problems, and all interviews and examinations were carried out by the same investigator on all occasions. If the volunteers met the inclusion criteria for the study, they were given written and verbal information about the aims and procedures of the study, and gave

written informed consent.

Thirty-one otherwise healthy men with reduced sexual desire aged 38 – 65 years (average 50.9 years), were enrolled.

This study was planned and performed as a randomized placebo-controlled double-blind study with a multi cross-over design. The total treatment period was 12 weeks. Half of the group started on 2 weeks treatment with the "active" product, switching every 2 weeks to "placebo", or back to "active" product. The other half started on "placebo".

In each of the treatment periods there were six cross-overs, meaning that the patient could either receive the following treatment plan: A-P-A-P-A-P-A-P-A-P-A-P-A. the effect was recorded weekly using an analogue scale, as described above, using sexual desire as the efficacy parameter. Possible side-effects were also recorded by the subjects.

THE SWEDISH STUDY

The product Libido was introduced to the Swedish market by an invitation to participate in a trial for a 3 – week period. Men with reduced sexual desire were enrolled (n=31) and asked to record their degree of sexual desire according to the following categories: (1) no increase in desire for sexual activity (2) minor increase (3) definite increase (4) major increase, and (5) very pronounced increase in desire for sexual activity.

MARKET RESPONSE

Information was obtained on the effect on sexual performance and the feeling of well-being of the individuals consuming the first commercial samples produced, and 32 men reported their responses on a weekly basis, on an evaluation form included with the product. After completing the treatment, they returned the evaluation form to the production company. These men initially had low sex drive. The age of the participants raged from 37 - 74 years. Fourteen of the men were between 57 and 74 years and initially recorded almost complete lack of sex drive to satisfy their partners and themselves. Four of those had not been able to complete a sexual satisfying act during the last 2 - 4 years. The rest of the group were younger and middle-aged men, ranging from 37 - 55 years of age, who wanted to increase the frequency of sexual intercourse.

RESULTS

Study 1

The results for the group that started with Libido and continued with placebo are illustrated in Fig. 1, and those for the group that started on placebo and transferred to Libido are shown in Fig. 2. Fig 1 shows an increase in the reported sexual desire during the first 3 weeks of the trial when the patients were given Libido. The relatively high score for the first week of placebo treatment is due to the residual effect of the preceding Libido treatment since there was no washout period.

The average score for sexual desire during the third week of treatment was with Libido on a visual analogue scale was 7.80 cm (SD +/- 1, 6; n=16), while the score for the third week of placebo treatment was 0, 25 cm (SD +/- 0.05; n=16), a statistically significant difference in favor of Libido (P> 0.001). These results suggest that Libido leads to significantly better stimulation of sexual desire than does placebo treatment. The study also indicated that the major increase in sexual arousal occurs 2-3 weeks after the start of treatment and that this treatment has a declining residual effect during the weeks after the treatment is stopped. None of the participants reported any side-effects either on Libido or placebo treatment.

Study 2

Table 1 summarizes the result of this study. A statistical comparison of the average scores in the three periods using Students t-test (first Libido period versus first placebo period, etc.) shows a significant difference in favor of Libido in all three periods (p< 0.05). Switching from Libido to placebo a carry-over effect was always observed during the first week, and even after 2 weeks on placebo. None of the individual volunteers returned to their baseline score during the placebo period. A 2-week interval, without a wash-out period is rather a short period as, in most cases, it is 6 – 10 days before any changes are observed. As there was no wash-out period between treatments, the carry-over effects from the Libido treatment to the placebo are considerable.

Over periods of treatment as short as 2 weeks, 58% of the individuals who basically had a very low sex drive, experienced enhanced sex drive.

The response profile of two of the patients in the treatment group P-A-P-A are shown in Fig. 3.

Figure 4 shows the profile of two patients treated with the schedule A-P-A-P-A-P. the response profiles of these patients, especially those in Fig. 3, show a marked pattern of response, generally having higher scores on Libido and lower scores on placebo.

The illustrated patient profiles were selected randomly. Similar response profiles were seen for the majority of the patients.

THE SWEDISH STUDY

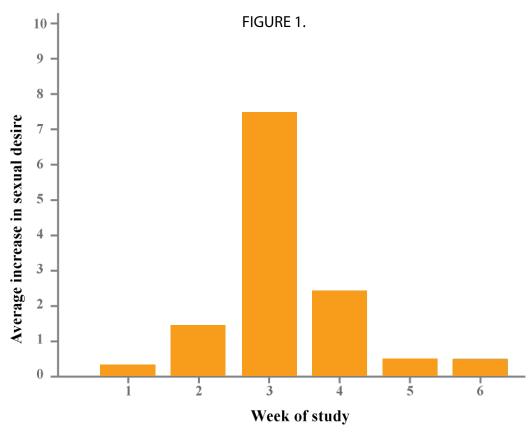
The data from this study are summarized in Table 2. These data indicate that during the 3-week period of Libido treatment, 83.9% of the men experienced an increase in their desire for sexual activity; 45.2% experienced major or very pronounced increases. None of the participants reported any side-effects on the Libido treatment.

MARKET RESPONSE

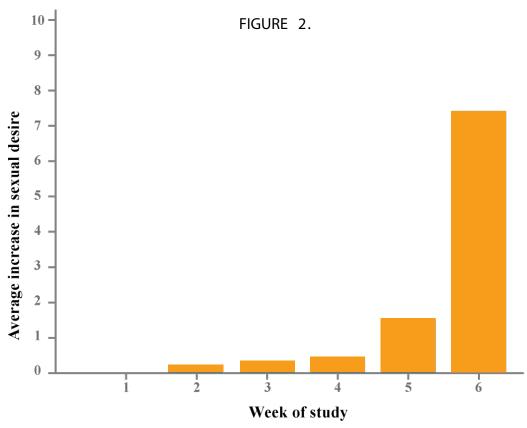
Data collected from consumers of the first produced samples of Libido were very encouraging, especially among the older and middle-aged men. The four oldest men were able to have successful intercourse after 2 weeks' consumption, and during the third week they reported 2 – 3 satisfactory sex acts.

For men who had been unable to satisfy their partners sexually for extended periods, this was a great change which affected their self-esteem and level of happiness.

Of the 14 men between 57 and 73 years of age, 12 experienced great improvements and wanted to continue taking the product, and two recorded no effect. One of these two was, however, receiving treatment for coronary problems. Eight of the younger men experienced an increase to 3 – 5 times their initial sex drive (on the scale from 1– 10). The rest (10 men) reported smaller, but noticeable and favorable changes in their sex drive (1-2 times), and wanted to continue taking the product.



Average scores for increase in sexual desire, based on a visual analogue scale from 0 (no change) to 10 (very pronounced change), of 16 healthy men (aged 47 – 60 years) who were treated with Libido for the first 3 weeks and with placebo for the following 3 weeks.



Average scores for increase in sexual desire, based on a visual analogue scale from 0 (no change) to 10 (very pronounced change), of 16 healthy men (aged 47 - 60 years) who were treated with placebo for the first 3 weeks and with Libido for the following 3 weeks.

Average scores for sexual desire in 31 otherwise healthy male volunteers with reduced sexual desire. Volunteers were given alternating 2-week phases on Libido or placebo treatments for 12 weeks. Half of the group started with the placebo and half with the Libido treatment.

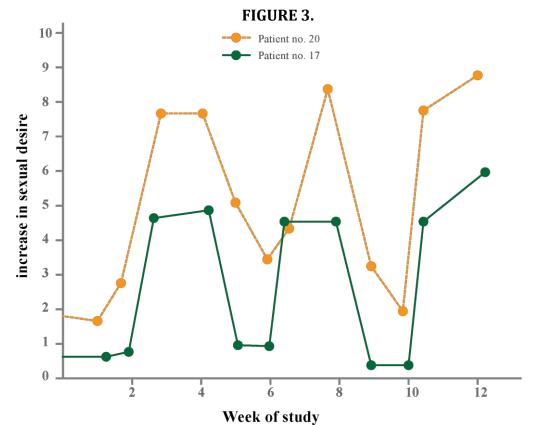
	Average Score for Sexual Desire*
Initial	1.51 ± 0.30
First Libido Period	2.82 ± 0.65
First Placebo Period	2.12 ± 0.48
Second Libido Period	2.43 ± 0.56
Second Placebo Period	2.31 ± 0.50
Third Libido Period	3.00 ± 0.60
Third Placebo Period	2.56 ± 0.63

^{*}Scores were recorded weekly, based on a visual analogue scale from 0 (no charge) to 10 (very pronounced change).

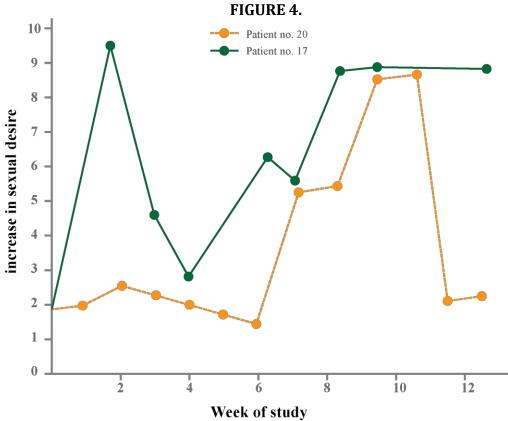
Table 2

Percentage of men showing increased sexual desire when 31 male volunteers, with reduced sexual desire, were treated with Libido for 3 weeks.

Change in Sexual Desire	Percentage of Men Showing Change
No Increase	16.1
Minor Increase	29.0
Definite Increase	9.7
Major Increase	19.4
Very Pronounced Increase	25.8



Changes in the scores for increase in sexual desire, based on a visual analogue scale from 0 (no change) to 10 (very pronounced change), in two men from a group of otherwise healthy men with reduced sexual desire who were given alternating 2-week phases on active treatment with libido or on placebo for 12 weeks, starting with placebo (P-A-P-A-P-A).



Changes in the scores for increase in sexual desire, based on a visual analogue scale from 0 (no change) to 10 (very pronounced change), in two men from a group of otherwise healthy men with reduced sexual desire who were given alternating 2-week phases on active treatment with libido or on placebo for 12 weeks, starting with placebo (A-P-A-P-A-P).