

YTE™ - AN EXTRACT OF FERTILIZED, PARTIALLY INCUBATED HEN EGGS.

The avian egg is an important source of nutrients, containing all the proteins, lipids, vitamins, minerals and growth factors required by the developing embryo, as well as a number of defence factors to protect against bacterial and viral infections. Moreover, eggs are now understood to contain substances with biological functions beyond basic nutrition, and extensive research has been undertaken to identify and characterize these biologically active components (Kovacs-Nolan J, Philips M, Mine Y: Advances in the value of eggs and egg components for human health. J. Agra Food Chem. 2005; 53:8421-31)

YTE™ is a patented extract from fertilized, partially incubated hen eggs, obtained through separation of oligopeptides from the total mass. These have molecular weights of 0.5 – 1.8 kD and are able to pass freely through the digestive barrier. These embryonic peptides work via elevation of 17-ketosteroid levels in the adrenal glands which improve anabolism through increased synthesis of androgens and a decrease in the catabolic hormone cortisol, which offers multiple benefits.

Initially, a less processed powder using the whole content of the egg (excluding shell) was used. Administration was in powder form in sachets. The taste of the product was not considered as acceptable to the public. Later (from 1999) separation of inactive parts were performed before further processing, hence providing a more concentrated powder. This was first planned for use in tablets, but tableting proved difficult due to hygroscopic properties. The present product in hard-gel capsules has been on the market since 2001. The difference between the original powder (as used in clinical work prior to 1999) and the current product equates to 1:1.79, i.e that 1.79 g of old product corresponds to 1 g of the currently available YTE™.

Initial trials with the original product were of experimental character and have not been reported. These gave, however, grounds for expectations of libido enhancing properties, improvement of stamina and muscle strength, mood enhancement and also other properties.

The first structured studies were performed during 1992 (*ref 1*) in order to investigate the effects on sexual desire with a follow-up during 1992/93 (*ref 2*) with the same purpose. Both of these studies were double-blind, placebo-controlled studies. These two studies were published in an article in the Journal of International Medical Research in 1997 (*ref 4*) together with the conclusions of an open post-marketing study performed in Sweden (*ref. 3*). This last study supports the findings of the two placebo-controlled studies, but cannot be used as documentation alone.

As it is known that anti-depressant medication often leads to decreased sexual lust and performance, a small pilot-study in patients on anti-depressant medication (SRI) for a minimum of 6 weeks were performed in Denver, Colorado during 1996/97. Although a small sample size, this study gave statistically significant results. (*Ref 5*)

At the same time an animal study was performed in Japan in order to study the effects on sexual behaviour of YTE™ in rats. The results of this study is consistent with the findings in

the human studies – further documenting the findings that YTE™ has a stimulating effect on the sexual desire and behaviour.(*ref. Pre-clinical 1*)

In order to study the effects on physical performance, muscle size etc a study was performed during the same period – also in Denver, Colorado. As creatine is widely used among body builders, this substance was used as placebo treatment, while a combination of YTE™ and creatine was used as active treatment. As the effects of creatine are known, this study can be regarded as a test against creatine (as placebo) and no treatment (given the documented effects of creatine). The result of this showed that the addition of YTE™ gave a significant increase in motivation (mental effect) as well as a non-significant improvement in strength and muscle size. On this basis we can conclude that YTE™ has a tendency to increase the effects of creatine in bodybuilding, i.e. a positive effect in strength and muscle size. (*Ref. 6*)

A hypothesis was during this period established that the clinical effects seen were due to hormonal effects. A study into the hormonal effects were subsequently performed in Oslo, Norway, into the hormonal effects of a single dose of YTE™. This study was designed solely with the aim of testing potential hormonal changes as a result of a large, single dose of YTE™ and showed that YTE™ may significantly reduce cortisol levels and improve the cellular uptake of testosterone – thus supporting the hypothesis that these hormonal effects may help explain the clinical effects seen. (*Ref. 7*)

Another study was performed during the same period on 14 elite soldiers of the Norwegian Armed Forces into muscular strength, restitution time and quality of life, but the details of this study are missing. (At the time, Med-Eq was only periferically involved in the process.)

Further studies

Med-Eq has sponsored two studies into the mood enhancing properties of YTE™. These studies use the present recommended dose of 4 tablets/day of 420 mg each. The results of these studies have been submitted for publication and are not available until publication is granted.

Several studies have also been performed into the effects in memory enhancement, and the results of these studies are under processing with the intention of submitting for publication.

Conclusions

It may be stated that available clinical and animal studies provide sufficient documentation that YTE™ has a stimulatory effect on sexual lust and behaviour – in the population in general as well as in patients experiencing lack of sexual lust due to anti-depressant medication.

It may also be stated that YTE™ strengthens the effect of creatine and this may be of value to people exercising and building muscles. (The Norwegian Army study also indicated that YTE™ alone gave improvements in muscle strength and restitution time.) The available studies in this area are, however, less well designed and reported than in the libido area.

The Academy of Sports study shows that YTE™ has an effect on the cortisol levels in the blood and the cellular uptake of testosterone. There are no indications that the intake of YTE™ causes an increased production of testosterone!

YTE

Pre-Clinical Studies

1. Effects of Fertilized incubated Shell Eggs on sexual Behavior of Male Rats 1996

Investigator: S. Kawashima et al, Zenyaku Kogyo Co, Ltd, Japan

Test subjects: 3 groups of 10 (n=30) rats – one group received YTE, one group non-incubated eggs and the third group the solvent vehicle.

Dose: 2x 583mg of unprocessed material per kg bodyweight over 3 weeks. (corresponding to 6501 mg/kg of YTE™)

Design: 3 string placebo-controlled behavioural study during 3 weeks.

Parameters: mounting frequency, intromission frequency, ejaculation frequency, mount-intromission-ejaculation latencies, reflexive erection test (after 3 weeks), blood samples and autopsy.

Results: Mounting frequency significantly higher in active group vs control groups.

Statistically significant difference in ejaculation frequency. Improvement of intromission frequency not statistically significant. Mounting-intromission-ejaculation latencies not statistically significant difference. No statistical difference in reflexive erection. No statistically significance in development of testosterone levels.

Clinical Studies

1. "A randomised placebo-controlled study of "Libido" on sexual lust in middle-aged , healthy men" 1992

Investigator: Erling Thom PhD. Oslo, Norway

Participants: n= 16 healthy male volunteers between 47 and 60 years (average 52.5) with reduced sexual lust. Average weight 84 kg, height 181 cm, BMI 25.6

Dose: 2 x 3 g of unprocessed material. Corresponds to a daily dose of 3.35 g of YTE™

Design: Group A (n=8) obtained active for 3 weeks, and subsequently placebo for 3 weeks.

Group B (n=8) obtained placebo for 3 weeks, and subsequently active for 3 weeks.

Parameters: Visual analogue score of 10 cm every week at end of week self-assessment of improvement in sexual lust.

Results: Participants had a significantly higher score on VAS scale at the end of 2nd and 3rd week during Active period vs Placebo period.

Comments: Study reported as study 1 in published article (4)

2. "A randomised placebo-controlled study of "Libido" on sexual desire in healthy middle-aged men" 1993

Investigators: Dr. KO Svendsen, Dr. Einar Christiansen. Statistics: Erling Thom PhD. Oslo, Norway

Participants: n=31 healthy male volunteers between 38 and 65 years (average 50.9)
Dose: 2 x 3 g of unprocessed material. Corresponds to a daily dose of 3.35 g of YTE™
Design: Two groups receiving alternately active-placebo or placebo-active for 6 periods of 2 weeks (3x2 weeks of active and 3x2 weeks of placebo = 12 weeks)
Parameters: Visual analogue score self-assessment at end of every week of improvement of sexual lust.

Lab.tests of testosterone levels in n=11.

Results: There is a tendency of higher scores in active periods than in placebo periods, but the difference is not significant. 40 – 50 % of the study subjects have no effect.

Testosterone levels increased by on average 25 % during the study period, but were well within normal testosterone levels in a healthy population.

Comments: Study reported as study 2 in published article (4)

3. “The Swedish Study”

Investigator: Bjødne Eskeland PhD. Statistics: Erling Thom PhD.

Participants: n=31 male volunteers. No data on age available.

Dose: 2x3 g of unprocessed material. Corresponds to a daily dose of 3.5 g of YTE™.

Design: This was an open, uncontrolled marketing study in healthy volunteers recruited through ads throughout Sweden. The study was performed without medical supervision. All participants took active substance over 3 weeks.

Parameters: 5 point scale of increase in sexual desire - self assessment.

Results: 54.9 % reported definite – very pronounced increase, while 16.1 % reported no increase.

Comments: Study reported as Swedish study in published article (4)

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

Authors: B Eskeland, E Thom, KOB Svendsen. Published in the J. of International Med. Research 1997

This is an article summarizing the 3 studies referred to above.

5. The Effect of “Libido” on decreased sexual Desire associated with Anti-Depressant Medication. 1996/97

Investigator: Dr. Kjell Törnblom, University of Denver, Colorado

Participants: 11 persons taking anti-depressant medication and having experienced reduced sexual lust in connection with this. 8 persons -5 male and 3 female – completed the study.

Age of male participants 29 – 67 years, females 26 – 39 years.

Dose: 2 x 6 tablets of 420 mg unprocessed material (5 g) corresponding to a daily dose of 2.8 g of YTE™.

Design: Single blind, placebo-controlled study over 6 weeks. Initially 3 weeks of active - followed by 3 weeks of placebo.

Parameters: a. Derogatis Affects Balance Score (DABS) self assessment at start-up, after 3 weeks and after 6 weeks.

b. 9-point Likert scale assessing sexual lust and behaviour at same times + after 2 and 5 weeks.

Results: Statistically significant improvements in Intensity of sexual desire, Frequency of sexual desire, energy, and confidence and self esteem.

6. Effects of nutritional Supplements designed to promote lean tissue accretion on body composition and strength performance. 1996/97

Investigator: Dr. Kjell Törnblom, University of Denver, Colorado

Participants: Originally 39 volunteers (mixed gender) of which 26 healthy volunteers completed the study. Of these 7 were advanced bodybuilders and 19 actively training at a local gym.

Dose: 5 g of unprocessed material corresponding to a daily dose of 2.8 g of YTE™

Design: 17 participants took a combination of YTE + creatine as “active” and 9 took creatine as placebo. Single blind placebo-controlled study over 6 weeks. The difference in change between the two groups is regarded as due to YTE.

Parameters: Measurement of muscle mass, strength.

Results: Significant improvement in training motivation. Almost significant change in strength and physical change.

7. Effects of Protein Supplements on the natural Production of Hormones subsequent to hard Training. 1996/97

Investigator: Bjødne Eskeland PhD in cooperation with researchers at the Norwegian Academy of Sports. Oslo, Norway.

Participants: 9 advanced (male) bodybuilders of 20 – 30 years of age.

Dose: Single dose: 200 g of unprocessed powder corresponding to 111 g of YTE™

Design: Single dose double-blind cross-over study with 7 days wash-out period between in order to test the immediate effects of the active substance on hormone production.

Parameters: Laboratory tests of testosterone, insulin, kortisol and growth hormone in blood samples

Results: Participants receiving active substance had a significant reduction of kortisol compared to placebo as well as increased cellular uptake of testosterone and higher insulin levels.