

FEW CLINICAL TRIALS ON “DR. J. HORNY OX-XS” INGREDIENTS EFFICACIES (FOR HEALTH CARE PROFESSIONALS ONLY)

MACA (*Lepidium meyenii*)

1. Dording CM et al. (2008) conducted a double-blind, randomized study of Maca root (*L. Meyenii*) to determine, whether Maca is effective for selective-serotonin reuptake inhibitor (SSRI)-induced sexual dysfunction. Workers found that three grams of Maca root per day may alleviate SSRI-induced sexual dysfunction, and may also have a beneficial effect on libido.
Dording CM, et al. A double-blind, randomized, pilot dose-finding study of maca root (*L. meyenii*) for the management of SSRI-induced sexual dysfunction. *CNS Neurosci Ther.* 2008 Fall;14(3):182-91.
2. Gonzales G.F et al. (2001) conducted a study to determine the effect of a 4-month treatment with tablets of Maca on seminal analysis in nine adult normal men aged 24-44 years old. Study Results showed that treatment with Maca resulted in increased seminal volume, sperm count per ejaculum, motile sperm count, and sperm motility by mechanisms not related to LH, FSH, PRL, T and E₂.
Gonzales G.F. et al. *Lepidium meyenii* (Maca) improved semen parameters in adult men. *Asian J Androl* 2001 Dec; 3: 301-303.
3. In another double blind placebo-controlled, randomized trial by Gonzales group (2002) The trial demonstrated an effect of Maca (3000 mg per day) on sexual desire but this effect is independent of changes in scores for depression and anxiety tests and serum testosterone levels. Workers believe effect of Maca on sexual desire could be because of any unknown chemical signal, i.e., phyto-oestrogens.
Gonzales G.F. et al. Effect of *Lepidium meyenii* (MACA) on sexual desire and its absent relationship with serum testosterone levels in adult healthy men. *Andrologia* 34, 367–372 (2002).
4. Zenico and others carried out a double-blind clinical trial on 50 Caucasian men affected by mild erectile dysfunction (ED), randomised to treatment with Maca root (2400 mg), or placebo. Study data supported a small but significant effect of Maca supplementation on subjective perception of general and sexual well-being in adult patients with mild ED.
Zenico, et al. Subjective effects of *Lepidium meyenii* (Maca) extract on well-being and sexual performances in patients with mild erectile dysfunction: a randomised, double-blind clinical trial. 2009 Blackwell Verlag GmbH *Æ Andrologia* 41, 95–99.

TRIBULUS TERRESTRIS

1. Sixty-seven women with hypoactive sexual desire disorder were randomly assigned to Tribulus extract (7.5 mg/day) or placebo for 4 weeks. At the end of the 4th week, patients in the Tribulus group had experienced significant improvement in their total FSFI, desire, arousal, lubrication, satisfaction & pain.
Elham Akhtari et al. Tribulus terrestris for treatment of sexual dysfunction in women: randomized double-blind placebo - controlled study. *Journal of Pharmaceutical Sciences* 2014, 22:40.
2. Sixty-five men with abnormal semen evaluation were included in a study in which they were prescribed with Androsten[®] (250 mg of Tribulus *terrestris* dried extract per capsule). The results demonstrated that an increase in dihydrotestosterone levels. Complete semen analysis evaluated at the end of treatment showed significant enhancement in sperm concentration, motility and liquefaction time. Protodioscin, (the main phytochemical component of Tribulus) is known to convert testosterone into dihydrotestosterone, which plays important roles in male attributes.
Salgado et al. Effect of oral administration of *Tribulus terrestris* extract on semen quality and body fat index of infertile men. *Andrologia* 2016; 1–6. wileyonlinelibrary.com/journal/and.
3. Recently, in a study based on hospital records of female patients of reproductive age, presenting sexual dysfunction, and treated with 250 mg Tribulus extract (one tablet thrice daily for 90 days). It is concluded that the *T. T* extract is safe and effective in the treatment of female sexual dysfunction
Barboza Gama et al. Clinical Assessment of *Tribulus terrestris* Extract in the Treatment of Female Sexual Dysfunction. *Clinical Medicine Insights: Women's Health* 2014;7 45–50.

4. Tribulus increases sperm count as well as motility levels when it is taken for 30 days. This is a good supplement for men and women to increase their sex drive. *T. terrestris* works by stimulating the anterior pituitary gland to release LH, which is responsible for stimulating the testes to produce testosterone.

M. Akram et al. Tribulus terrestris Linn.: A review article. Journal of Medicinal Plants Research Vol. 5(16), pp. 3601-3605, 18 August, 2011.

ANTIOXIDANTS

1. A systematic review of randomized studies was conducted by **Ross and others** to evaluate the effects of oral antioxidants on sperm quality and pregnancy rate in infertile men. 14 of the 17 (82%) trials showed an improvement in either sperm quality or pregnancy rate after antioxidant therapy. Ten trials examined pregnancy rate and six showed a significant improvement after antioxidant therapy. The use of oral antioxidants in infertile men could improve sperm quality and pregnancy rates.

Ross et al. A systematic review of the effect of oral antioxidants on male infertility. Reproductive Healthcare Ltd. Published by Elsevier Ltd. Reproductive Bio Medicine Online (2010) 20, 711– 723.

2. Administration of antioxidants to infertile men has been assessed in numerous clinical studies with at least 20 reports highlighting its effect on measures of oxidative stress in human spermatozoa. Studies results revealed that 19 of the 20 showed a significant reduction relating to some measure of oxidative stress in these cells. Strong evidence also supports improved motility, particularly in asthenospermic patients. However, of these studies, only 10 reported pregnancy-related outcomes, with 6 reporting positive associations.

Parviz Gharagozloo and R. John Aitken. The role of sperm oxidative stress of oral antioxidant therapy. Human Reproduction, Vol.26, No.7 pp. 1628–1640, 2011.

3. Infertile men possess substantially more sperm DNA damage than do fertile men, damage that may impact negatively on reproductive outcomes. In this era of assisted reproductive technologies there is mounting concern regarding the safety of utilizing DNA-damaged spermatozoa in this setting. Therefore, it is important to identify strategies that may reduce sperm DNA damage.

Zini and others at Royal Victoria Hospital, McGill University, Canada reviewed the literature on antioxidants and sperm DNA damage. The data suggest that dietary antioxidants may be beneficial in reducing sperm DNA damage, particularly, in men with high levels of DNA fragmentation.

Armand Zini & Maria San Gabriel & Abdulaziz Baazeem. Antioxidants and sperm DNA damage: a clinical perspective. J Assist Reprod Genet (2009) 26:427–432.

HORNY GOAT WEED (HERBA EPIMEDII)

1. is improving sexual and neurological functions. This efficacy is found to be related to the potent anti-oxidative ability and its flavonoid components, with icarrin as the main effective constituent

Stephen Cho Wing Sze, Yao Tong, Tzi Bun Ng, Chris Lok Yin Cheng and Ho Pan Cheung. Herba Epimedii: Anti-Oxidative Properties and Its Medical Implications. Review; *Molecules* 2010, 15, 7861-7870

2. In the “CHM the herb tonifies the kidney and fortify the yang for patterns of kidney yang deficiency with such symptoms as impotence and infertility

Bensky D, Clavey S and Stoger E (2004). *Chinese Herbal Medicine: Materia Medica 3rd Ed.* Seattle (WA): Eastland Press.

3. Also, in the “Oriental materia medica” It is indicated that the traditional application of this herb is the impotence. The herb has aphrodisiac actions mainly because it stimulates secretion of semen causing the filling up of the scrotum, thereby stimulating the sensing nerves and indirectly promoting sexual desire. Hsu H-Y, Chen Y-P, Shen S-J, Hsu C-S, Chen C-C Chen, Chang H-C (1986). *Oriental materia medica: a concise guide.* Long Beach (CA): Oriental Healing Arts Institute.

(All these scientific papers are available upon request)