CLINICAL

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MARS AND VENUS: THE LOW DOSE MEDIATORS OF SEXUALITY

MANAGING THE HYPOACTIVE SEXUAL DESIRE DISORDER (HSDD) WITH THE AID OF PHYSIOLOGICAL REGULATING MEDICINE

RIASSUNTO

Hypoactive Sexual Desire Disorder (HSDD) symptoms are – according to DSM-IV-TR (2000) – deficient or absent sexual fantasies and desire for sexual activity.
In this paper we present the analysis of the efficacy of two drugs (GUNA VENUS and GUNA MARS), composed according to the guidelines of the Physiological Regulating Medicine (PRM), in treating DDSI.
– Fifteen females and 15 males suffering from DDSI have been treated with the two PRM drugs, according to the gender. These patients have been compared with 15 female patients and 15 male patients suffering from DDSI treated with placebo.

– It is concluded that the therapy with PRM drugs has been more effective than the one using placebo in order to improve the sexual desire and the patients' quality of life.

KEY WORDS **HYPOACTIVE SEXUAL DESIRE DISORDER, HSDD, SEXUALITY, PHYSIOLOGICAL REGULATING MEDICINE**

INTRODUCTION

Sexuality is a complex behavior that brings together several components (FIG. 1): biological, historical, relational, psychological, environmental, cultural and of gender that operate influencing the individual towards the sexual experience in a functional or dysfunctional way (Simonelli et al, 2006).
To consider a sexual problem exclusively from an organismic point of view would limit and darken the psychosocial items related to it.

On the other hand a sexual disorder evaluating only from the phsycho-behavioral point of view would be likely to underestimate the presence of organic alterations that may be the cause of it or the contributing cause.
The Biological medicine - as it respects

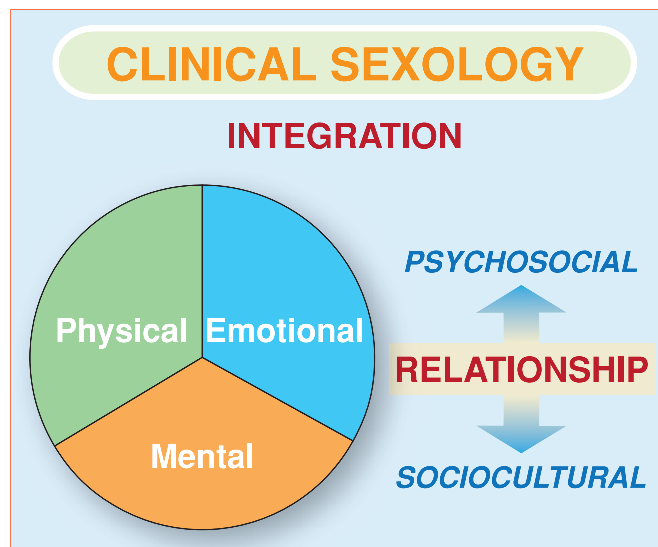


FIG. 1

the individuality of the person, just because it considers the psycho-biological unit of the individual - well suits the needs of patients who require treatment that is not just aimed at eliminating symptoms, but cares the patient and his discomfort caused by the dysfunction.

As a matter of fact, the risk to prescribe a drug treatment aimed solely at reducing symptoms, is that sexuality could become the source of psychological and physical discomfort, and therefore the *primum movens* of distress. This would contradict what the World Health Organization (WHO) advocated in agreement with the World Association for Sexual Health (WAS): *"A state of complete physical, emotional, mental and social well-being related to sexuality is not simply the absence of disease, dysfunction or illness. Sexual health requires a positive and respectful approach to sexuality and sexual relations, as well as the possibility of having pleasant and safe sexual experiences, free from coercion, discrimination and violence. In order to reach and maintain sexual health, the sexual rights of all people should be respected, protected and fulfilled"* (2002).
Based on the above, agreeing with the statement made by other specialists, the approach to sexual problems have to be defined and integrated in a bio-psycho-social model (Simonelli et al, 2006).
In this work - from the eighth of Integrated medicine, which is the basis of Physiological Regulating Medicine - analyzes the contribution of two complex drug called **GUNA-VENUS** and **GUNA-MARS**, respectively, indicated for the female and the male patients presenting issues related to a decrease in sexual desire.

Such pharmaceutical complex remedies are designed with the aim to promote the rebalancing of the emotional boost towards the sexual relationship through the restoration of an adequate psico-neuro-endocrine-immunologic and metabolic enzymatic framework, taking into account, also and above all, an action on the thymus axis tone.

OBJECTIVES

The aim of this study was to evaluate the efficiency and effectiveness of two pharmaceutical complex remedies formulated according to the principles of the Physiological Regulating Medicine, named

GUNA VENUS for the female sample group (15 patients) and **GUNA MARS** for the male sample group (15 patients).
The data obtained were compared with two control groups (15 female patients and 15 male patients) treated with placebo.
Both the patients of the *verum* group and those of the control group had hypoactive sexual desire disorder (HSDD) (FIGG. 2, 3).
The treatment was performed for two consecutive months (60 days).

PATIENTS AND METHODS

PATIENTS

The methods used for the assessment of the *verum* group and the control group are:
- The **Female Sexual Function Index (FSFI)** (Rosen, 2000) for females.
This tool is a questionnaire that provides an assessment of female sexual function, developed with the aim of determining the specific importance of certain variables (desire, sexual arousal, lubrication, orgasm, satisfaction, pain) in experimental studies.
The results arising from the use of the questionnaire mainly concern the experiences related to the sexual intercourse by the woman that is the experience and the quality of the sexual intercourse.

The FSFI - besides being the most common instruments used in research on

SEXUAL DYSFUNCTIONS

A sexual dysfunction is characterized by anomaly of the process underlying the cycle of sexual response or by pain associated to the sexual intercourse.
Sexual dysfunctions can occur during different phases of the sexual response.

Diagnosis and Statistics Dosssier on mental disorders IV TR (DSM-IV-TR). Ed. Masson, 2000.

FIG. 2

BASIC CHARACTERISTICS OF SEXUAL DYSFUNCTIONS (ICD-10)

The person is not able to live the sexual intercourse the way he/she would like

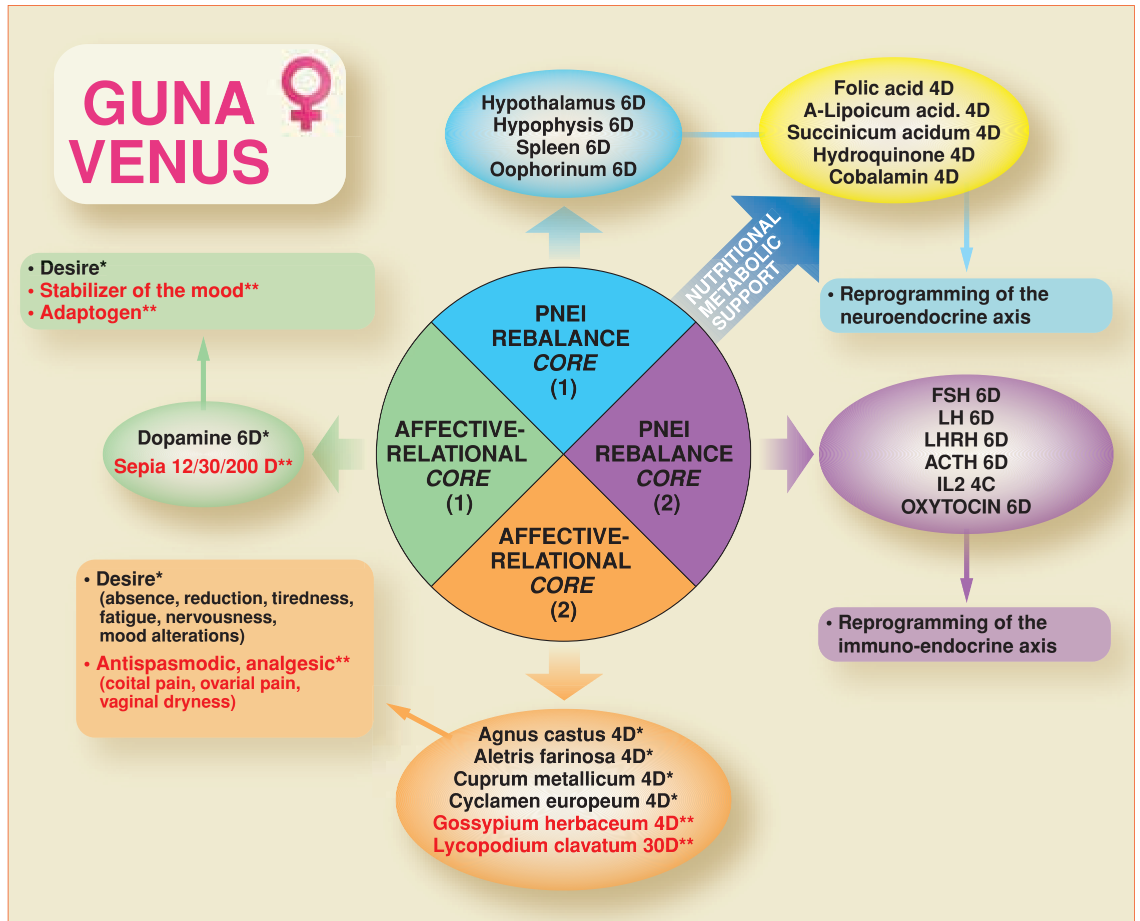
The dysfunction occurs frequently but can in some occasions be absent

The dysfunction occurs for at least a period of 6 months

The dysfunction is not totally due to other mental and/or behavioural and/or physical disorders or to pharmacological treatments

FIG. 3

TAB. 1



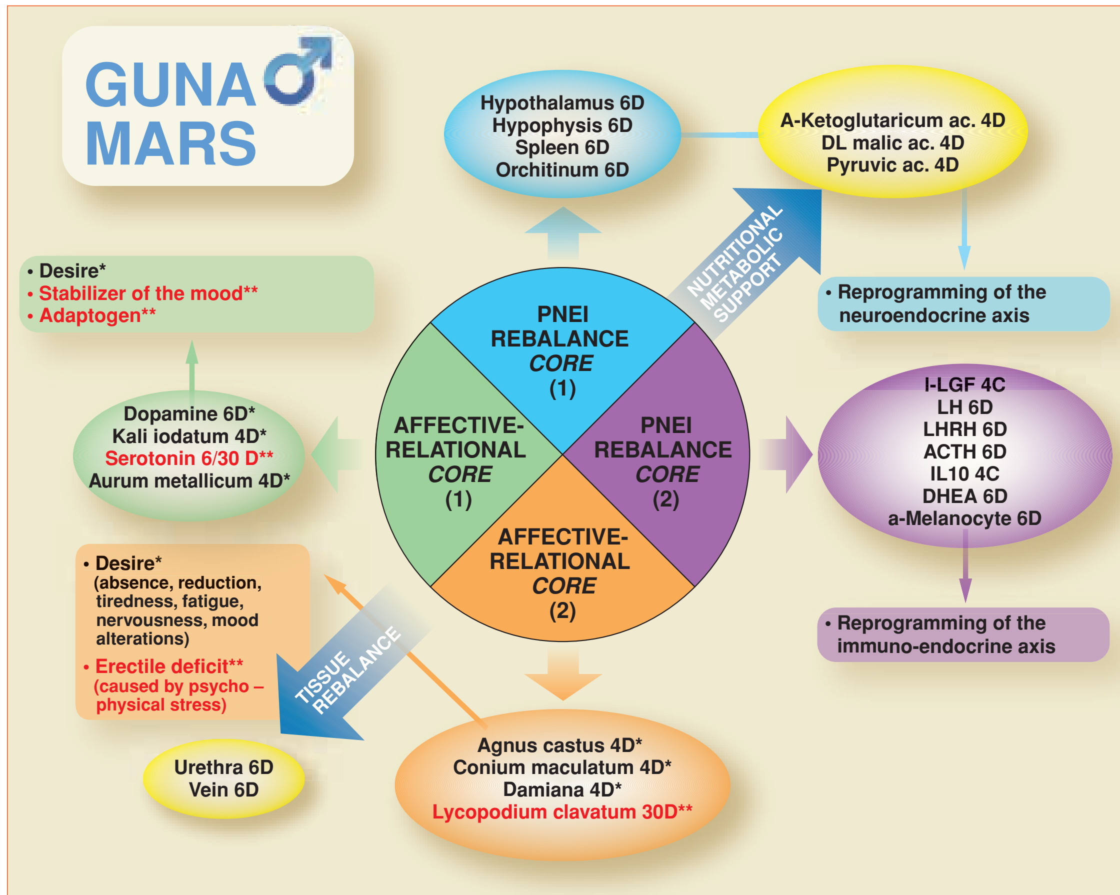
sexual field - has been particularly useful in this work to describe which components related to sexual experience were redefined in terms of quality.
The FSFI, in fact, discriminate – from a qualitative point of view – pathological subjects from non-pathological ones, and provide valid indexes to describe and understand the diversity of issues concerning female sexuality.
The items included in FSFI are:

- **Desire**: the desire or sexual interest is a feeling that includes the desire to have a sexual experience, be receptive to sexual partners and think about or fantasize about sex.
In particular the frequency with which one feels sexual desire or interest is analyzed as well as the level reached.
- **Sexual arousal**: sexual arousal is a feeling that encompasses both physical and mental. It can include feelings of warmth or tingling in the genitals, lubrication or muscle contractions.
In the FSFI this area is investigated based on the frequency and level of excitement reached and security to achieve arousal during sexual intercourse, as well as the relative frequency of satisfaction in feeling excited at the same.
- **Lubrication:** the lubrication can be considered as the physical counterpart of sexual excitement with which the woman can also experience to what extent is her desire of penetration. For the description of this area information on the frequency and the difficulty of achieving adequate lubrication is given, as well as how many times (in percentage) the woman is able to maintain lubrication and the difficulty in maintaining an adequate lubrication until the conclusion of the sexual intercourse.
- **Orgasm:** orgasm identifies the acme of pleasure, whether physical or mental. Is, from physical point of view, in a series of contractions in the vaginal and perineal floor producing a state of intense pleasure and well-being. The area is studied through the frequency, difficulty and satisfaction in reaching orgasm.
- **Pain:** the discomfort or the real pain experienced by women during sexual intercourse is evaluated through the frequency with which it appears during and after vaginal penetration.

- **The International Index of Erectile Function-15 (IIEF-15)** (Rosen, 1997) with regard to study sample and control men.

The questionnaire is mainly intended to diagnose the erectile dysfunction (ED) but it also analyzes other areas related to male sexuality as orgasm, sexual desire, satisfaction during intercourse, and the general well-being.
The ED provides quantitative information, in terms of scores. The IIEF-15 allows the classification of the ED in "severe" (score 6-10), "moderate" (score 11-16), "mild" (score 17-25), and "absent" (score 26-30).
The other fields usefully considered in the questionnaire provide qualitative information and support for a correct clinical diagnosis for which no quantitative cut-off is provided.
The areas assessed by IIEF-15 are:

- **Erectile Function:** It indicates the capacity of penetration of the partner dur-



TAB. 2

ing intercourse or the erectile capacity through masturbation.

This area is investigated through a series of questions concerning the frequency with which the patient is able to get an erection and how often these erections allow penetration.

Also the frequency with which one is able to penetrate the partner is assessed, as well as to maintain the erection after penetration until the end of the intercourse. The last question refers to the confidence one has to achieve and maintain an adequate erection during sexual intercourse.

- **Orgasm:** it describes possible problems concerning ejaculation.

This area is very important because the information obtained report about the frequency with which one reaches orgasm as well as possible orgasm without ejaculation.

- **Sexual desire:** this area analyzes the desire to have a sexual experience, also through masturbation and not just through sexual intercourse, the thought of sex or the frustration due to the lack of sexual activity. The patient is asked to state how often he has felt sexual desire and its subjective evaluation of the sexual desire that he experienced.
- **Satisfaction during the intercourse:** this is certainly the most complex area of investigation as it bases its analysis on the correct knowledge and description of subjective and relationship elements related to the partner. In particular this analysis considers the frequency with which the subject attempts to have sexual intercourse, the degree of satisfaction experienced during the intercourse and the pleasure they give.
- **General well-being:** it includes the subjective assessment of how much one's sexual life is satisfactory and to what extent sexual relationship with the partner is positive. Regarding the issues concerning female arousal disorders also the last revision of the classification of female sexual dysfunction has been taken into accout (Basson et al, 2005).

METHODS

The study groups and the controls groups who participated in the study were diagnosed according to the criteria of DSMIV-TR as they showed a Hypoactive Desire Disorder.

After the diagnosis, to the patients included in the *verum* group were prescribed the pharmaceutical complex remedies **GUNA VENUS** (15 female patients) and **GUNA MARS** (15 male patients); at the beginning of the therapy and after two months, **FSFI** (for female patients) and **IIEF-15** (for males) were also administered.

To the control group a placebo was prescribed and, also in this case, to the female patients (No. 15 patients) **FSFI** was administered and to the male patients (No. 15 patients), **IIEF-15**.

The study was carried out in single-blind, controlled, randomized trial.

DESCRIPTION OF THE COMPONENTS OF GUNA-VENUS AND GUNA-MARS

The two complex remedies are described and the two main areas of

intervention, called "core", are highlighted.
Althoughthey have specific characteristics, each complex remedy has an affective-relational core and a core of PNEI rebalance as it is described below:

▶ GUNA VENUS (TAB. 1)

Affective-relational core: *Agnus castus* 4X; *Aletris farinosa* 4X; Cuprum metallicum 4X; *Cyclamen europeum* 4X; *Gossypium herbaceum* 4X; *Lycopodium clavatum* 30X; *Sepia* 12/30/200X, Dopamine 6X.
This group of components form a nucleus that is very important in situations characterized by decline or lack of desire associated with behavioral manifestations of vegetative-like weakness, such as fatigue, "nervousness", mood alterations (*Agnus castus, Aletris farinosa*, Cuprum metallicum, *Cyclamen europeum*). What also makes this pharmacological complex remedy specific is the component acting on problems connected with pain associated with intercourse (*Gossypium herbaceum, Lycopodium clavatum*). Dopamine and *Sepia* are have an effect on the desire and ace on as mood stabilizers.
PNEI core rebalancing: Hypothalamus 6X, Hypophysis 6X, Spleen 6X, Oophorinum 6X, FSH 6X, LH 6X, LHRH 6X, ACTH 6X, IL2 4C, Oxytocin 6X, Folic acid 4X, A-Lipoicum Acidum 4X, Succinicum acidum 4X, Hydroquinone 4X, Cobalamin 4X.
The compounds of this group provide the right stimulus or the proper rebalance of the neuroendocrine axis.
In addition to these: FSH 6X, LH 6X, LHRH 6X, ACTH 6X, IL2 4C, Oxytocin 6X for a reprogrammation of the immuno-endocrine axis.

▶ GUNA MARS (TAB. 2)

Affective-relational core: *Agnus castus* 4X, *Conium maculatum* 4X, *Damiana* 4X, *Lycopodium clavatum* 6X, Dopamine 6X, Kali iodatum 4X, Serotonin 6/30X, Aurum metallicum 4X, Urethra 6X, Vein 6X.
All these single remedies have a marked effect on human sexual functions such as the decrease or loss of sexual desire with or without problems related to erection and ejaculation.
In particular about *Agnus*, *Conium* and *Damiana* there is a large homeopathic-homotoxicological literature on their positive action in respect of the issues mentioned above.
Particularly worth to point out is the action of *Lycopodium* in erectile dysfunctions due to psycho-physical stress. The activity of the pharmacological complex tend to manifest itself also from an organic point of view through the action of the components Urethra and Vein.
The more distinctly affective component acts through a "push" to restore a reasonable mood with a positive and enjoyable sex life (Dopamine, Kali iodatum, Serotonin, Aurum metallicum).

PNEI core rebalancing: Hypothalamus 6X, Hypophysis 6X, Spleen 6X, Orchitinum 6X, I-LGF 4C, LH 6X, LHRH 6X, ACTH 6X, IL10 4C, DHEA 6X, A-Melanocyte, A-Ketoglutaricum acidum 4X, DL malic acidum 4X Pyruvic acidum 6x.
Again there is an endocrine-metabolic "action block" having the function to redefine the PNEI Axis.

DESCRIPTION OF THE SAMPLE AND OF THE CONTROL

The female sample is composed of 15 patients while the male one of 15 patients. For the admission to the study the patients included should:

- correspond to the clinical diagnostic criteria of DDSI according to the classification of DSM-IV-TR (APA, 2000);
- not show problems at the endocrine level;
- sign a special release for the use of their data, for the sole purpose of research, while preserving their anonymity (as required by the Law Decree; June 30th, 2003, No. 196, "Code for the Protection of Personal Data");
- not have organic diseases related to the pathology studied;
- not have carried out or, alternatively, have suspended medical treatment and/or psychotherapy since at least four months.

- To the patients of the *verum* group a daily dose **GUNA-MARS** was administered.
- To the female patients of the *verum* group a daily dose **GUNA-VENUS** was administered.

The same criteria were used for the inclusion in the study of the control group. This group consisted of 15 female patients and 15 male patients with a HSDD diagnosed with the above criteria. To the male and female patients of the control group a daily dose of placebo was given.

The treatment lasted 60 consecutive days for both the *verum* and the control group.

RESULTS

▶ The **female *verum* group** showed an increased percentage in all areas investigated with the FSFI (desire +36,4%; excitation +37,6%; lubrication +24,6%; orgasm +40,3%; satisfaction + 62,3%; pain -7,9%) (TAB. 3).
The **areas which have provided a statistically significant response** ($p < 0.05$) at the end of the observation period were **satisfaction, orgasm, excitement, desire** and **lubrication** ($p < 0.0001$).

The area concerning pain had no statistical evidence as the patients in the *verum* groups did not present problems related to pain during or after intercourse.

Let's analyze in detail the items that make up the surveyed areas in the *verum* group:

- **Desire:** increased values especially for the subjective evaluation. The patients reported to prove greater

RESULTS IN WOMEN

Variable	% MEAN INCREASE	
	GUNA VENUS	PLACEBO
DESIRE	+ 36,4	+ 1,8
AROUSAL	+ 37,6	+ 5,3
LUBRICATION	+ 24,6	+ 3,7
ORGASM	+ 40,3	+ 6,8
SATISFACTION	+ 62,3	+ 5,6
PAIN	– 7,9	0

In the verum group, the percentage increase in the average of the different categories (before *vs* after the treatment) is very high in the area Satisfaction (+62,3%), Orgasm (+40,3%), Arousal (+37,6%) and Desire +36,4%).

TAB. 3

desire towards the partners during the therapy.

- **Excitation:** this is the variable that recorded the biggest increase.
A marked improvement rate was also recorded in other items concerning excitation, such as frequency, satisfaction and confidence in achieving a valid and compelling excitement.

- **Lubrication:** the item that had an improvement rate great interest was the frequency with which patients were able to maintain the lubrication until the completion of sexual activity.

- **Orgasm:** what is substantially increased in percentage is the patientes' perception of satisfaction and their ability to reach orgasm.
At the same time there has been an improvement in the frequency and a decreased difficulty in reaching the climax.

- **Satisfaction:** this is the area where surely there were better results as the percentage increase was significant in all items, especially worth noting is the increase in the satisfaction given by emotional contact with your partner.
Then, there is the satisfaction of the sexual intercourse, and in particular the evaluation of how the patients have experienced satisfaction during their whole sexual life.

- **Pain:** this item was not evaluated because none of the patients had pain related disorders.

• With regard to the **control group** the data analyzed at the end of the observation period showed an increased percentage of the areas desire (+1,8%), arousal (+5,3%), lubrication (+3,7%), orgasm (6,8%), satisfaction (+5,6%). The area concerning pain did not show percentage changes (0%).

- From the statistical point of view none of the above areas has achieved significant results.

▶ **The male *verum* group** showed an increased percentage in all areas investigated by means of IIEF-15 erectile function(+19,6%, satisfaction during intercourse +33,3%, orgasm +15%, sexual desire + 44,1%; general well-being +38,7%) (TAB. 4). .

The **areas which have provided a statistically significant response** (p <0.05) at the end of the observation period were **satisfaction during intercourse** (p <0.005), **sexual desire** (p <0.0001), **general well-being** (p <0 , 0001).
The areas related to the erectile function and to orgasm did not have statistical evidence as the *verum* group did not have problems related to these functions.
Just to look more deeply in the items included in the surveyed areas the following can be observed:
- **Satisfaction during intercourse:** a significant percentage increase has been observed for what concerns the frequency with which patients have tried to have sexual intercourses, the personal satisfaction and the pleasure experienced.
- **Sexual desire:** in this scale, there has been a significant increase of the desire to have a sexual experience. Specifically, the patients perceived as being significantly increased firstly the level of desire and then the frequency with which they had sexual desire.
It should be noted that this area includes not only the desire for sexual intercourse but also for masturbation.
- **General well-being:** the items concerning the general well-being are related to the level of overall sexual life

RESULTS IN MEN

Variable	% MEAN INCREASE	
	GUNA MARS	PLACEBO
ERECTILE FUNCTION	+ 19,6	+ 2,5
SATISFACTION	+ 33,3	+ 4,9
ORGASM	+ 15,0	+ 4,0
DESIRE	+ 44,1	+ 5,8
GENERAL WELLBEING	+ 38,7	+ 5,0

In the verum group, the most important results in terms of percentage increase in the average of the different categories (before *vs* after the treatment) have been reported in the areas Desire (+44,1%), Wellbeing (+38,7%) and Satisfaction (+33,3%).

TAB. 4

satisfaction and sexual relationship with the partner. Both characteristics showed a percentage increase.
What has mostly responded to the therapy was the perception of the satisfaction with the partner.
With regard to the erectile function and the orgasm, these two areas, while they have showed increases in rates, nevertheless they have not reached statistical significance. This also in view of the fact that patients did not show any problem related to the mentioned areas.

• With regard to the **control group**, the analysis of the data at the end of the observation period showed that there was a percentage improvement in 4 of the 5 areas investigated with IIEF-15 erectile function +2,5%; satisfaction during intercourse +4,9%; orgasm +4%; sexual desire +5,8%; general well-being +5% but **none of them had statistical significance (p <0.005)**.

DISCUSSION

The analysis of these figures show that the treatment of the female group with **GUNA-VENUS** gave statistically significant results (p <0.005) in comparison with the placebo group.

In particular - considering the individual areas FSF – it is worth noting that the area where there was a stronger effect of the drug was linked to the **satisfaction** (+62,3%) experienced by patients in emotional contact with their partner.

This is extremely important as it is just from satisfaction that grows the awareness about the wish to start a sexual relationship. If the patient considers and feels rewarding sexual experience, in terms of personal satisfaction, she will be motivated to repeat that experience.
Basson et al (2005) have developed a circular model of female sexuality by identifying four stages: desire, excitation, orgasm and resolution/satisfaction. Compared to the previous models an important new element is added: *"the association of the physiological phase of excitation resolution through a process of subjective evaluation of the experience in terms of satisfaction/dissatisfaction"* (Simonelli et al, 2006).

It is just this subjective evaluation of the experience that can act as a brake to the repetition of the sexual act, if this gives them frustration and/or dissatisfaction (negative feedback). In contrast, a sexual intercourse with feelings of emotional involvement, or otherwise positive, acts as a reinforcing element (positive feedback) for repeating the experience. What emerges from this study is in line with a therapy that not only tends to "stimulate" the sexual response but also acts on the psycho-behavioral substrate of experience, so as to make perceive as rewarding this experience. It is no coincidence that, in terms of percentage, the areas that had showed greatest increase, after the **satisfaction** area, have been those related to **orgasm** (+40,3%), **arousal** (37,6%), and **desire** (+36,4%).

The latter, in fact, represent the reasons why the person tends to repeat the intercourse. The pleasure one gets from being sure to be able to reach a full satisfaction - and at the same time feel satisfied of the level reached by his/her excitement - is what increases the will to repeat this experience.

The four areas listed above, are the faces of a global indivisible reality acting synergistically for the mutual reinforcement, that ultimately favour the personal satisfaction during intercourse. The complex medication prescribed seems to to have acted in this direction, by harmonizing the sexual response and not forcing it. The sensation reported by patients (although not statistically valuable) was that they felt more involved in the sexual intercourse and then experienced an increased sexual desire towards the same approach.
As regards the introduction of **GUNA-MARS** the same considerations may be applied, although with their own features and specifications. The control group had no statistically significant improvements in any area, the *verum* group gave statistically significant results in the areas **satisfaction during intercourse, sexual desire** and **overall well-being** analyzed by the IIEF-15.
In particular, the **desire** is the area that showed a greater percentage increase (+44,1%). Just the relative deficit in this area was the motivation which led patients to seek treatment and in which there was the biggest improvement. The area that has benefited most was referred to the level of desire associated with the frequency with which the patient felt sexual desire.

Quantity + frequency affected the will to have a sexual intercourse and the frequency with which the person felt excited. The importance of this can be well understood as we look into what Leiblum (2002) stated; he believes that the way we live and express our sexual interest is not determined by biological forces only, but mainly by socio-cultural and relational conditions.
In men, even more than in women, sexuality is tied to performance, this leads back to the model mentally elaborated to set up the relationship with the other.

Very often this is the product of what the culture of our society to which we belong requires as a model. A loss of desire can lead to impotence, although this is not the first difficulty to overcome. To improve the trust relationship with ourselves and especially "to feel" really interested in the sexual relationship is an act of awareness that is essential for a good approach to sexuality. To appreciate the desire to have a sexual intercourse puts the person in an attitude of receptivity that means itself predisposition to the other.

The desire is linked with the sensation of feeling good not only with themselves but also in relation to the partner. It is no coincidence that in the present work, the entries that received the largest increase in therapy were those relating to general well-being

(+38.7%) and satisfaction during intercourse (+33.3%). Also in this case the motivation is the same as for the female group, where these three components are integrated with each other by acting synergically and are aimed at an increased desire.
The subject, subjected to a therapy that promotes firstly the well-being - acting through the proper balancing of the entire PNEI network - feels a greater "predisposition" towards the other and, consequently, the other will be more inclined to accept it.

All this confirms the thought of Alberoni (1986): "*the desire and the eroticism do not recall a total cancellation and a loss of the self, but a dialectical process between continuity and discontinuity.*"
- Biological therapy seems to act just for this process, as it is not in contrast with any action of a chemical nature, it tends to preserve the correct inner dialogue to favour the relationship with oneself and with the other.

CONCLUSIONS

The results are interesting and demonstrate that a therapy based on biological regulation principles can intervene favourably in issues related to sexual desire.
In this work, the two complex remedies **GUNA-VENUS** and **GUNA-MARS** demonstrated to be effective on DDSI that is the problem for which male and female patients decided to look for a medical advice.

In particular, the integration of drugs formulated according to a synergy and complementary principle, in different low dose, has probably allowed the body to choose and take what it needs in that moment for its homeostasis. Drugs formulated according to this principle may therefore be useful in the context of the entire range of sexual dysfunctions as they act, according to the issue presented, from different points of view, according to the alteration of the physiological sexual response showed by the patient.
- In conclusion it is possible to assess that the approach to biological medicine - especially in issues related to sexuality - must be researched and investigated to ensure that patients are treated in their potentiality and reconsidered also from the psychobiological point of view according to the individual reactive capacity, while respecting the unity that is proper in humans.

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