

Hypoactive Sexual Desire Disorders (HSDD) of female sexuality - Disease or symptom of an underlying health problem?

THOUGHTS ABOUT HSDD AND THE SIDE EFFECTS OF ITS TREATMENT

ESSAY

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by

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DECLARATION OF INDEPENDENCE

This is a statement of authorship assuring that this thesis has been made independently and without unauthorised assistance.

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Abstract

According to DSM-5 Hypoactive Sexual Disorder Disease (HSDD) is a persistent lack of physical desire for sex and missing sexual activity, or sexual thoughts or fantasies or low libido. HSDD can be caused by an amount of reasons and depending on the reason the treatment is different; if the treatment takes place at all.

Some investigations were performed how HSDD can be treated. HSDD can occur occasionally or constantly. It affects up to 43% of woman in the United States [1].

The purpose of this essay is to deliver an empirical examination of the treatment of HSDD during a twenty-four week, random, double-blind, placebo controlled, safety and efficacy trial of Flibanserin (100 Milligrams) administered orally once daily in premenopausal women with Hypoactive Sexual Desire Disorder (HSDD) in the United States.

Introduction

Suffering from HSDD is often reported at different life moments and can take on a variety of occurrences. For example it can be made up in loss of desire of sex, orgasms or pain. HSDD can occur occasionally or constantly.

HSDD could be due to mental health problems as well as a new sexual relationship or side effects by certain medications.

Estimations state that 1 out of 10 women suffer from HSDD.

Stegenga [1] asserts it is controversial if „female sexual arousal disorder is a disease in the DSM-5-characterizing women who have little interest in sex“ is a disease at all. He also clues that some diseases are culture-bound and only exist in particular places. But in order to develop medical help it had to be considered as a disease and put it into the DSM-5 system. HSDD can be caused by

- depressions or anxieties
- heart and blood vessel disease
- neurological conditions
- gynaecological conditions
- medications
- emotional stress
- heavy hormonell dysfunctions
- heavy obesity
- abortion or loss
- sexual abuse

and sometimes it is a combination of several reasons affecting organically, hormonal, urological, neurological or psychological aspects.

But then HSDD as applicable for diagnosing people of all genders was removed from DSM-5, which was published in 2013. The new diagnosis for females is Female Sexual Arousal/Interest Disorder, the diagnosis of which requires 3 out of the following 6:

- 1) An absent/reduced interest in sexual activity;
- 2) absent/reduced sexual thoughts or fantasies;
- 3) absent/reduced initiation of sexual activity and being typically unreceptive to partner's initiatives;
- 4) absent/reduced excitement or pleasure during sexual activity in 75%–100% of sexual encounters;
- 5) absent/reduced interest/arousal in response to sexual cues; and
- 6) absent/reduced genital or non-genital sensations during activity in 75%–100% of encounters.

Treatments

GINKGO

Some investigations were performed how HSDD can be treated, e.g [2], Ginkgo biloba extract (GBE), a naturally occurring substance from the ancient Gingko tree is supposed to have a positive effect by increasing peripheral blood flow and also by relaxing the person. It can be combined with a behavioural based therapy to improve the affect. It has no considerably serious side effects.

ACUPUNCTURE

Another rather natural approach is applying acupuncture [3]. In [3] a 5-weeks treatment, à 45/60 minutes placed twice weekly was validated and we know that acupuncture can improve sexual function in women. After five weeks the treatment was found with significant improvements from baseline in overall sexual function, while distress due to symptoms and anxiety levels were found to be significantly reduced. Acupuncture has no relevant serious side effects.

FLIBANSERIN

A pharmaceutic product named Flibanserin is seen to be „the new female libido pill“, the „pink Viagra“ and is manufactured by Sprout Pharmaceuticals sponsored by Boehringer Ingelheim.

In [5] it was investigated a twenty-four week, random, double-blind, Placebo controlled, safety and efficicady trial of Flibanserin (100 Milligrams) administered orally once daily in premenopausal woman with Hypoactive Sexual Desire Disorder in the United States. The result is illustrated in this chapter. The current primary outcome measures are the change from baseline to week 24 in the Score of the Female Sexual Function Index Desire Domain (FSFI). The FSFI is a questionnaire for accessing key dimensions of sexual function in women.

The timeline of the study is visualised here:

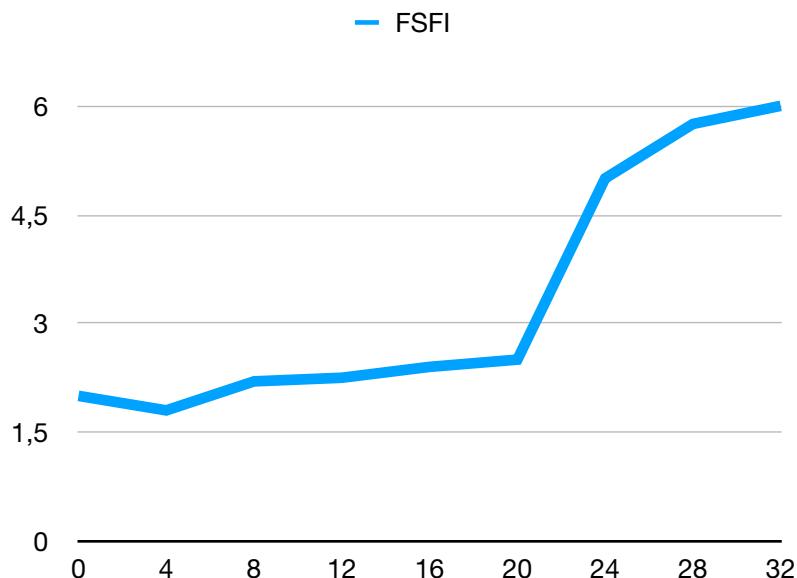
Study startet	Primary Completion	Study Completion	Last Update	Results Posted
31st Oct 2009	31st Dec 2010	28th Feb 2011	19th May 2014	19th May 2014

FLIBANSERIN 100 MG PLACEBO

Serious Adverse Effects	4	2
Not affected by serious Adverse Effects	539	545
Other Adverse Effects	237	68
Not affected by other Adverse Effects.	306	479

You can find a more detailed description of the study in [6].

As a result of a questionnaire for assessing key dimensions of sexual function in women you can view the change of the FSFI outcome after 24 weeks below. The scale consists of 19 items assessing sexual function over the past 4 weeks and yields scores in 6 domains: desire, arousal, lubrication, orgasm, satisfaction, and pain. The 2 items in the



desire domain are scored from '1' to '5'. The raw scores of the 2 items are added together and then multiplied by the domain factor of 0.6. Thus, the score of the desire domain ranges from 1.2 to 6.0. The higher the score on the desire domain, the higher the level of reported sexual desire [6]. The patients recorded their sexual events in an eDiary. In [6] you can also find the table of side effects, which can be considered as a disadvantage of the medical treatment. Especially nervous system disorders like

	Organ System	Event Term	Flibanserin 100 mg	Placebo
Other	Nervous system disorders	somnolence	14.36% (78 of 543)	3.47% (19 of 547)
Other	Nervous system disorders	dizziness	10.31% (56 of 543)	1.1% (6 of 547)
Other	Gastrointestinal disorders	nausea	7.55% (41 of 543)	2.19% (12 of 547)
Other	Nervous system disorders	fatigue	5.89% (32 of 543)	3.29% (18 of 547)
Other	Respiratory, thoracic and mediastinal disorders	upper respiratory tract infection	5.52% (30 of 543)	2.38% (13 of 547)
Serious	Hepatobiliary disorders	biliary dyskinesia	0.18% (1 of 543)	0% (0 of 547)
Serious	Hepatobiliary disorders	cholelithiasis	0.18% (1 of 543)	0% (0 of 547)
Serious	Infections and infestations	gastroenteritis	0.18% (1 of 543)	0% (0 of 547)
Serious	Injury, poisoning and procedural complications	cervical vertebral fracture	0.18% (1 of 543)	0% (0 of 547)
Serious	Musculoskeletal and connective tissue disorders	musculoskeletal chest pain	0.18% (1 of 543)	0% (0 of 547)

somnolence and dizziness could be asserted, but also nausea and fatigue and upper respiratory tract infection.

Additionally, if you consider [7], it is highly questionable if it advisable to take the risk of a medical treatment with those side effects for the following reasons: [7] states that HSDD is not a disease at all; it is an ambiguous, highly contested diagnosis. Furthermore there are multiple sources of sexual desire; desire is shaped by psycho-social and interpersonal factors; variation is normal [7]. Additional [7] doubts the scientific neutrality and proposed that the assessment instruments used to formulate Boehringer Ingelheim's claims about sexual desire and distress were developed by industry funded researchers. This might be a conflict of interest.

Summary - a controversial discussion

It is still controversial if HSDD can be called a disease a priori, or if a lack of sexual desire could also be received positively and get turned into a self-chosen form of life. In medical circles it is clearly classified as a sexual dysfunction or even a psychological respectively mental disorder. In other rather sociologically approaches it is seen as a highly contested diagnosis. It is presumably questionable what has to be classified as 'normal' as a sexual desire. It could be due to the cultural setting: era, location, ethnicity, sexual identity, etc, [7]. Historically, women were pathologized for exhibiting too much or too less sexual desire. Since the 'sexual revolution,' standards of "normalcy" have reversed. In social media there is already the expression „asexuality“ originated to describe the lack of interest in sexuality, as a self decided form of sexuality. Assumably asexual people would not need medical treatment.

Providing that the individual woman has the wish to get treated in order to increase her sexual desire there are several ways to do so, e.g. the natural way like Gingko or acupuncture. Another possibility is to get medical treatment through Flibanserin, which was illustrated in this essay. The side effects have to be precisely weighed against each positive effect. A change of FSFI from the baseline could be observed at week 24. Other side effects but not serious side effects like dizziness and somnolence occurred in an undesired amount and might weaken the possible positive effect of Flibanserin.

References

- [1] Stegenga, Jacob, 2018: „Care and Cure, An Introduction to Philosophy of Medicine“. The University of Chicago Press, page 80
- [2] U.S: National Library of Medicine, NCT Number NCT00034021, <https://clinicaltrials.gov/ct2/show/NCT00034021> last recalled on 8th October, 2022
- [3] U.S: National Library of Medicine, NCT Number NCT02070029, <https://clinicaltrials.gov/ct2/show/NCT02070029> last recalled on 8th October, 2022
- [4] Woloshin, S; Schwartz, LM. (2016) US Food and Drug Administration Approval of Flibanserin: Even the Score Does Not Add Up, JAMA Internal Medicine 176: 439
- [5] U.S: National Library of Medicine, NCT Number NCT00996164, <https://clinicaltrials.gov/ct2/show/NCT00996164> last recalled on 8th October, 2022
- [6] LONG ISLAND UNIVERSITY, Clinical Drug Experience Knowledgebase, NCT Number NCT00996164, <http://www.cdek.liu.edu/trial/NCT00996164/> , last recalled on 11th October, 2022
- [7] Prepared for FDA Advisory Committee Hearing on Flibanserin of June 18, 2021 by the New View Campaign, Fact Sheet HSDD, <http://newviewcampaign.org/flibanserin.asp> last recall on 14th October 2022