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Naltrexone in Compulsive Sexual Behavior Disorder: A Feasibility Study of Twenty Men

Josephine Savard, MD,[1,2] Katarina Görts Öberg, PhD,[2,3] Andreas Chatzittofis, MD, PhD,[1,4] Cecilia Dhejne, MD, PhD,[2,3] Stefan Arver, MD, PhD,[2,3] and Jussi Jokinen, MD, PhD[1,5]

ABSTRACT

Background: Compulsive sexual behavior disorder (CSBD) is a common disorder affecting different areas of life, although studies focusing on pharmacological treatment are sparse.

Aim: To investigate whether the opioid receptor antagonist naltrexone is feasible and tolerable and can provide symptom reduction in CSBD.

Methods: Twenty men aged 27−60 years (mean = 38.8 years, standard deviation = 10.3) with CSBD seeking treatment in an outpatient nonforensic clinic received four weeks of naltrexone 25−50 mg. Measurements were made before, during, and four weeks after treatment.

Outcomes: The self-assessment Hypersexual Disorder: Current Assessment Scale (HD: CAS) score was the primary outcome measure, and secondary outcomes were the Hypersexual Behavior Inventory (HBI) score, reported adverse effects, adherence to treatment, and dropouts.

Results: There was significant decrease on both HD: CAS and HBI scores during treatment with naltrexone. Even though some of the effects remained after treatment, the increased scores on HD: CAS indicated worsening of CSBD symptoms. The most reported side effects were fatigue (55%), nausea (30%), vertigo (30%), and abdominal pain (30%). However, there were no serious adverse effects leading to discontinuation of naltrexone.

Clinical Implications: Despite side effects being common, naltrexone seems to be feasible in the treatment of CSBD.

Strengths & Limitations: Being the first nonforensic prospective trial on naltrexone in CSBD, this study provides novel insights on a pharmacological intervention. However, owing to the small sample size and the lack of a control group, conclusions of effectiveness should be interpreted with caution.

Conclusion: Naltrexone is feasible and tolerable and may reduce symptoms of CSBD; nevertheless, future studies should ensure a randomized controlled procedure to evaluate possible effectiveness. **Savard J, Öberg KG, Chatzittofis A, et al. Naltrexone in Compulsive Sexual Behavior Disorder: A Feasibility Study of Twenty Men. J Sex Med 2020;XX:XXX−XXX.**

Key Words: Compulsive sexual behavior disorder; Naltrexone; Hypersexual disorder; Sexual addiction

INTRODUCTION

Until recently, there has not been specified diagnose criteria for the condition with excessive sexual fantasies, urges, and behaviors leading to significant impairment in life. In the latest revision of the Diagnostic and Statistical Manual of Mental Disorders (DSM), hypersexual disorder (HD)[1] was proposed to be included, although the diagnosis was finally not accepted. In the International Classification of Diseases version 10, excessive sexual drive could be coded as a sexual dysfunction, and recently, the World Health Organization has included compulsive sexual behavior disorder (CSBD) as an impulse control disorder in ICD-11.[2,3] The definition states the following: *"Compulsive sexual behavior disorder is characterized by a persistent pattern of*

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[1]Department of Clinical Sciences/Psychiatry, Umeå University, Umeå, Sweden;

[2]Anova, Karolinska University Hospital, Stockholm, Sweden;

[3]Department of Medicine, Karolinska Institutet, Stockholm, Sweden;

[4]Medical School, University of Cyprus, Nicosia, Cyprus;

[5]Centre for Psychiatry Research, Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden

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*failure to control intense, repetitive sexual impulses or urges resulting in repetitive sexual behavior. Symptoms may include repetitive sexual activities becoming a central focus of the person's life to the point of neglecting health and personal care or other interests, activities and responsibilities; numerous unsuccessful efforts to significantly reduce repetitive sexual behavior; and continued repetitive sexual behavior despite adverse consequences or deriving little or no satisfaction from it. The pattern of failure to control intense, sexual impulses or urges and resulting repetitive sexual behavior is manifested over an extended period of time (*eg, *6 months or more), and causes marked distress or significant impairment in personal, family, social, educational, occupational, or other important areas of functioning. Distress that is entirely related to moral judgments and disapproval about sexual impulses, urges, or behaviors is not sufficient to meet this requirement."*[2]

Thus, CSBD shares many features with the earlier proposed HD as symptoms include a persistent pattern of failure to control intense, repetitive sexual impulses or urges resulting in repetitive sexual behavior.

CSBD has been suggested to affect 3−6% of the population,[4] although higher estimates have recently been reported.[5] Furthermore, symptoms of compulsive sexual behavior are common in help-seeking men with paraphilic disorders.[6,7] Despite a high prevalence, only a small number of studies have evaluated the efficacy and tolerability of specific pharmacological treatments. For example, antiandrogen medications have been reported to decrease the frequency and intensity of sexual desire and subjective sexual arousal.[8] The use of antiandrogens, however, is often combined with high rates of side effects and is not considered a primary choice in a regular clinical setting if not accompanied by sexual behaviors with risk to offend others.[9,10] Instead, selective serotonin reuptake inhibitors might be alternatives in reducing compulsive sexual behavior.[8,11,12] Nevertheless, only one randomized controlled trial has examined the effectiveness of selective serotonin reuptake inhibitors and reported partial support for reducing compulsive sexual behaviors.[11] Finally, the opioid receptor antagonist naltrexone has been reported in case-series as an agent that may reduce both urges and behaviors associated with compulsive sexuality.[13−16] Naltrexone has also been reported effective in the treatment of other urge-driven disorders such as alcohol dependence and amphetamine dependence, as well as in broadly defined behavioral addictions (eg, pathological gambling and kleptomania).[17−19] The rewarding effect of alcohol is mediated partly via release of endogenous opioid peptides. Naltrexone blocks the opioid receptors and therefore prevents the reinforcing effects of alcohol.[17] Although many aspects of CSBD are not yet known, neuroimaging and genetic studies indicate a partial overlap with addiction disorders.[20−28] According to a recent review article, consistent reports show increased reactivity of the ventral striatum in CSBD during the anticipation of erotic stimuli supporting the Incentive Salience theory[29] that is of interest as naltrexone targets opioid receptors in this specific area.[24,26,28,30] In summary, the proposed mechanism of naltrexone in CSBD is through opioid-related modulation of the rewarding mesolimbic pathways.[14,16] Therefore, the aim of the present open pilot study was to investigate whether naltrexone is feasible, tolerable, and can provide symptom reduction in patients with CSBD.

METHODS

Ethics

The study was approved by the regional ethics review board in Stockholm (Dnr 2018/1265-31) and the Swedish Medical Products Agency (Dnr 5.1-2018-47747) and was conducted in accordance with the Declaration of Helsinki.

Participants

Participants who sought treatment for CSBD at ANOVA, a multidisciplinary center for research, assessment, and treatment in andrology, sexual medicine, and transgender medicine, at the Karolinska University Hospital, Stockholm, Sweden, were invited to participate in the study if meeting the threshold criteria. The study aimed to attract both men and women and to include 20 participants. Advertisement in newspapers and online was made, and the participants were enrolled between November 2018 and June 2019. To be eligible for the study, the participants had to meet the criteria of CSBD in ICD-11, and fulfill 3 of the 5 A-criteria and one of 2 B-criteria of the suggested DSM-5 conceptualization for HD as it was originally proposed.[1] Furthermore, the participants had to be between 18 and 65 years, to understand the Swedish language in oral and in written, have internet access, and be willing to participate in all study visits (ie, 3 visits, or 2 visits, and telephone consultation).

Exclusion criteria for participation were alcohol dependence or risk consumption (>14 units of alcohol per week for men) in the past month, illicit self-reported use of drugs in the past month or positive drug verification analysis, or ongoing opioid or benzodiazepine medication. Other exclusion criteria were severe psychiatric disorder such as current psychotic illness or severe depression requiring immediate treatment, change of concurrent medication or dosage in the last 3 months, sexual behaviors with high risk to offend other, or ongoing psychotherapeutic treatment. For safety reasons, pregnancy and/or breast-feeding lead to exclusion as well as a history of allergic reaction to naltrexone, elevated liver enzymes, serious physical illness, or a history of liver or kidney failure.

Procedures

An initial screening regarding compulsive sexual behavior and inclusion and exclusion criteria was made by telephone interview. Potential participants received information about the study and were invited to log into a secure web-based platform, leave a preliminary informed consent, and fill in questionnaires including details on personal information. Furthermore, detailed information on the protocol was provided including that

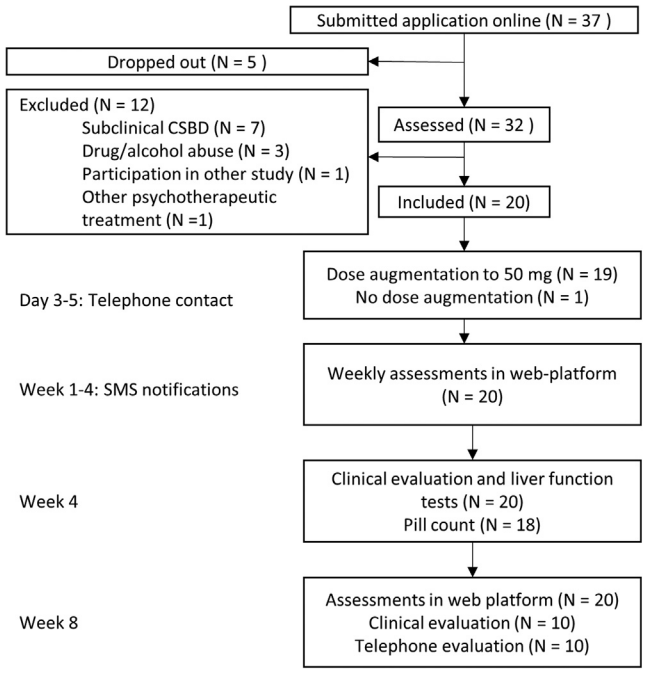

Figure 1. Participants' flow in an open prospective study of naltrexone in CSBD. CSBD = compulsive sexual behavior disorder.

participation was voluntary and could be interrupted at any time. The participants were thereafter evaluated face to face by a psychiatrist and a psychologist. The psychiatrist obtained the medical history, assessed for CSBD according to the ICD-11 criteria and for psychiatric diagnoses using the Mini International Neuropsychiatric Interview,[31] and gave detailed safety information on naltrexone. The study psychologist verified the participant's responses of sexual behaviors in the web-based questionnaires (eg, the Hypersexual Disorder Screening Inventory [HDSI]), conducted a structured interview addressing the criteria for CSBD and HD, as well as assessed for paraphilia(s) in accordance with the criteria specified in DSM-5. Participants were seen as eligible if both the psychiatrist and the psychologist agreed on the eligibility criteria and none of the psychiatric exclusion criteria. Eligible participants were enrolled after signing a written informed consent. Urine samples were screened for amphetamine, benzodiazepine, buprenorphine, cannabis, clonazepam, cocaine, fentanyl, methadone, opiates, oxycodone, and tramadol. Finally, the liver profile was evaluated; aspartate transaminase, alanine aminotransferase, gamma-glutamyl transpeptidase, and alkaline phosphatase. Figure 1 illustrates procedures after inclusion.

Outcome Measures

The hypersexual disorder: current assessment scale (HD: CAS) measures the severity of symptoms during the previous 2 weeks.[32] The scale consists of 7 items; 1 item covers current sexual behaviors and the remaining 6 items quantify number of orgasms, time spent on sexual behaviors, the use of sexual behaviors as coping, experienced control and negative consequences. Score range: 0−24.

The Hypersexual Behavior Inventory (HBI) is a 19-item scale validated in accordance to the DSM-5 criteria of HD.[33] The scale measures sex as coping, loss of control, and consequences. Score range: 19−95, cutoff ≥53.

The primary outcome measure was changes in HD: CAS, which has been used as an outcome measure in previous studies at ANOVA.[34,35] However, because there is no gold standard on how to measure clinical effect of pharmacological treatment in CSBD, the HBI assessment was used as a secondary outcome measure. All measurements have been translated to Swedish in a standard back-translation procedure.

Clinical Characteristics Measures

The Sexual Compulsivity Scale (SCS) is a 10-item validated scale that assesses compulsive sexual behaviors and urges.[36] Items are scored from 1−4. Score range: 10−40.

The HDSI screens for the proposed DSM-5 criteria of HD.[37] Five items cover the A-criteria, and 2 items cover the B-criteria. The items can be scored 0−4, and the criteria are considered to be fulfilled if scores are 3−4. In addition, the scale examines problematic sexual behaviors with a yes-no option on 6 specified sexual behaviors and a specifier "other behaviors."

The Kinsey Heterosexual−Homosexual Rating Scale assesses sexual orientation.[38] The scale ranges from 0−6 with 0 meaning exclusively heterosexual and 6 meaning exclusively homosexual.

The Montgomery-Åsberg Depression Rating Scale Self-rating consists of 9 items to assess for depressive symptoms.[39] Score range: 0−54.

The Hospital Anxiety and Depression Scale contains 14 items divided on 2 subscales measuring anxiety respectively depression.[40] Score range: 0−21 on each subscale.

The Alcohol Use Disorders Identification Test consists of 10 items that assess alcohol consumption, drinking behavior, and alcohol-related problems. Score range: 0−40, with ≥8 indicating harmful use in men.[41,42]

The Drug Use Disorders Identification Test consists of 11 items and screens for the use of drugs and drug-related problems.[43] Score range: 0−44.

Intervention

Naltrexone 50 mg (AOP Orphan Pharmaceuticals, Vienna, Austria) was provided from the Karolinska University Hospital pharmacy. The participants obtained 28 tablets free of charge and were instructed to start with 25 mg (half a tablet) for the first 3 to 5 days. If tolerated, the daily dosage was augmented to 50 mg for a total period of 4 weeks. In Sweden, naltrexone is exclusively indicated in the treatment of alcohol dependence with the recommended dosage of 50 mg per day. Being a feasibility study, the recommended dosage was not exceeded. Measures of compliance included pill count and self-reported adherence to treatment. Missed intake for more than 3 consecutive days was to be considered as noncompliance and a dropout.

Table 1. Baseline characteristics of participants (n = 20), with compulsive sexual behavior disorder

Baseline characteristics	Participants (*n* = 20)
Age, mean (SD)	38.80 (10.31)
Range	27–60
Country of birth, *n* (%)	
Sweden	17 (85)
Other	3 (15)
Civil status, *n* (%)	
Married, cohabitant, or registered partner	17 (85)
Unmarried	3 (15)
Children, *n* (%)	11 (55)
Highest education level, *n* (%)	
9-year compulsory school or less	1 (5)
Upper secondary	10 (50)
University	8 (40)
Other	1 (5)
Employment, *n* (%)	
Student	2 (10)
Working	18 (90)
Sexual orientation*, n (%)	
Exclusive heterosexual	14 (70)
Other	6 (30)
Problematic sexual behaviors**, n (%)	
Masturbation	19 (95)
Use of pornography	17 (85)
Sex with consenting adults	7 (35)
Cybersex	6 (30)
Telephone sex	1 (5)
Other sexual behavior	2 (10)
Paraphilic disorder, n (%)	1 (5)
Psychiatric characteristics, n (%)	
Diagnosis of anxiety disorder	5 (25)
ADHD	5 (25)
Other	3 (15)
Antidepressants	2 (10)***
ADHD medication	1 (5)***
History of depression	6 (30)
Anxiety disorder	7 (35)
Suicide attempt	2 (10)
Substance abuse	3 (15)
No current or previous psychiatric diagnosis, n (%)	6 (30)
Measurements, mean (range; SD)	
HDSI	19.90 (4–28; 6.08)
MADRS-S	17.80 (6–37; 9.90)
HAD anxiety	10.35 (2–20; 4.16)
HAD depression	7.80 (1–17; 4.72)
AUDIT	4.45 (0–11; 3.40)
DUDIT	0.30 (0–4; 0.92)

Assessments After Inclusion

The participants were encouraged to log into the web-based platform weekly to assess symptoms (eg, if experiencing any change in frequency or intensity of sexual urges or behaviors) by filling in HBI and SCS. Furthermore, questions were asked on compliance ("Have you continued with naltrexone?" with a yes/no alternative and possibility to state the date for discontinuation), how the treatment was perceived, and experience of adverse events. Every second week, HD: CAS was to be submitted. Although filling in the questionnaires was not mandatory and missing data would not lead to exclusion, SMS notifications were sent to remind the participants to fill the self-rating scales.

After 4 weeks, naltrexone was discontinued and the participants had a consultation with the study psychiatrist to assess for current symptoms of CSBD, psychiatric distress, and tolerability. Liver function tests were collected.

After additionally 4 weeks, the participants had a final consultation with the study psychiatrist, either by telephone or face to face, whatever the participant preferred.

Data Analysis

The skewness and kurtosis of the distributions were evaluated with the Shapiro-Wilks test, both outcome measures were considered to have normal distribution. The two-sided paired sample t-test was used to determine whether there were mean differences between baseline and designated measure points (mid treatment, end of treatment, and after treatment). The effect sizes were calculated using Cohen's d. The alpha was set at <0.05. For the statistical analyses, IBM SPSS Statistics 25.0 was used.

RESULTS

The participants

32 men were assessed for participation, of which 12 did not meet the assigned criteria and were excluded either by telephone or after face-to-face interviews. As can be seen in Table 1, the final cohort included 20 men with a mean age of 38.8 years (SD = 10.3 years). According to the Kinsey Heterosexual–Homosexual Rating Scale [25], a majority (70%) identified as exclusively heterosexual. The most reported problematic sexual behaviors measured with HDSI were masturbation (95%) and use of pornography (85%).

ADHD = attention deficit hyperactivity disorder; AUDIT = Alcohol Use Disorders Identification Test; DUDIT = Drug Use Disorders Identification Test; HAD = Hospital Anxiety and Depression Scale; HDSI = the Hypersexual Disorder Screening Inventory; MADRS-S = Montgomery-Åsberg Depression Rating Scale Self-Rating.
*According to Kinsey heterosexual-homosexual rating scale, **as responded in HDSI, ***stable dosage for at least 3 months.

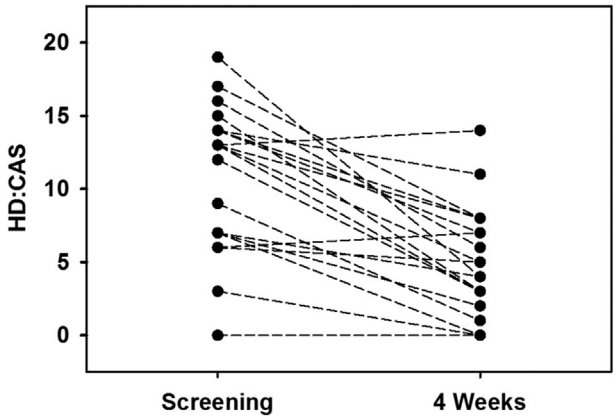

Figure 2. HD: CAS mean scores at baselne and after treatment (n = 20). HD: CAS = Hypersexual Disorder: Current Assessment Scale.

In regard of comorbidity, 11 of the participants were considered to have at least one current psychiatric diagnosis; anxiety disorder (25%), attention deficit hyperactivity disorder (25%), and adjustment disorder (15%). 2 participants were treated with antidepressants (ie, stable dose for > 3 months) and one with attention deficit hyperactivity disorder medication.

Adherence to Treatment and Tolerability

All participants (n = 20) declared that they had taken naltrexone during the study period of 4 weeks. 2 participants failed to return the empty blisters. In general, most declared to have missed less than 3 doses, and pill count indicated compliance (mean missed doses = 1.56; SD = 1.72).

In regard of safety, liver function tests were normal both before and after treatment, and no suspected unexpected serious adverse reaction or serious adverse event occurred.19 (95%) reported some adverse event. The mean of adverse events was 2.42 (SD = 1.07; range = 0−4). Most common were fatigue (55%), nausea (30%), vertigo (30%), abdominal pain (30%), apathy (15%), headache (10%), anxiety (10%), and sexual dysfunctions (10%). Although usually transient within the first days−week, 3 participants experienced symptoms for the whole treatment period. One of the participants remained at the dosage of 25 mg/day because of fatigue; thus, the other 19 were treated with 50 mg/day. At follow-up, the participants were asked if interested in resuming naltrexone therapy; yes (30%), no (15%), and I don't know (55%).

Outcome Measures

A 100% response rate was obtained at the designated time points. The self-reported symptoms of compulsive sexual behavior measured with HD: CAS decreased significantly during the use of naltrexone: the mean score of HD: CAS at baseline was 10.90 (SD = 4.98), which decreased after 2 weeks of treatment to 5.65 (SD = 4.00) and at end of treatment to 4.95 (SD = 3.75); Figure 2, Table 2. The changes of mean score at baseline compared to after 2 weeks (M = 5.25, 95% CI = 3.19−7.31, t(19) = 5.34, $P < .0001$, Cohen's $d = 1.19$), and end of treatment (M = 5.95, 95% CI = 3.90−8.00, t(19) = 6.07, $P < .0001$, Cohen's $d = 1.36$) were statistically significant, and the effect sizes were large. At follow-up (ie, four weeks without naltrexone), the mean had increased to 8.10 (SD = 4.89), although still significantly lower than at baseline with a medium effect size (M = 2.80, 95% CI = 1.03−4.57, t(19) = 3.31, $P = .004$, Cohen's $d = 0.74$). Figure 3 illustrates the changes in HD: CAS during the study protocol. Secondary outcome measured with HBI also showed significant reduction (Table 2).

DISCUSSION

In the present study, naltrexone was feasible, tolerable, and significantly decreased symptoms of CSBD measured with HD: CAS. The decrease in HD: CAS scores from 11 to 5 could be considered a clinically significant reduction. Similar results were seen on the measures HBI and SCS. Although some of the effects remained 4 weeks after discontinuation with naltrexone, the smaller effect size indicates worsening of CSBD symptoms. Being the first prospective study focusing exclusively on naltrexone in a nonforensic sample of CSBD, the present study provides important information from a clinical perspective and could be the foundation for future studies on pharmacological treatment of CSBD.

One could argue that the adverse events, for example, nausea or fatigue, might shift the participant's focus from sexual urges and behaviors. However, most adverse effects were reported as mild and transient, which should not affect the sexual drive more than for a short time. However, quite a large number of participants were uncertain when asked about interest in resuming treatment with naltrexone at the end of the study protocol. Although not systematically assessed, many participants were keen on having information on other available treatments in the clinic including cognitive behavioral therapy. The partially maintained reduction of CSBD symptoms at follow-up and thus less need for treatment may also contribute to the hesitation. Post-treatment evaluations of naltrexone in alcohol dependence also indicate that the therapeutic effect decline, although the effects on heavy drinking still reached statistical significance 3−12 months after the treatment was discontinued.[44] The similar observation in CSBD seen in this study needs to be confirmed in a placebo-controlled trial including longer treatment and follow-up period.

Despite the side effects being common at start, all the participants completed the study. No serious adverse events occurred, and there was no pathological raise of liver function tests, which indicates the naltrexone intervention to be feasible and tolerable. Our results suggest the tolerability of naltrexone to be similar in CSBD as in alcohol dependence.[45]

Table 2. Assessments of sexual behaviors at baseline and designated measure points

Measurements	Mean	SD	Median	Range	Statistics (t-test)		
					t-value*	*P*-value*	Cohen's *d**
HD: CAS baseline	10.90	4.98	13.00	0–19			
HD: CAS mid treatment	5.65	4.00	5.50	0–12	5.34	$P < .0001$	1.19
HD: CAS end of treatment	4.95	3.75	4.50	0–14	6.07	$P < .0001$	1.36
HD: CAS follow-up	8.10	4.89	9.00	0–14	3.31	$P = .004$	0.74
HBI baseline	72.80	13.09	74.50	42–89			
HBI mid treatment	47.75	19.64	52.00	19–77	6.66	$P < .0001$	1.49
HBI end of treatment	42.90	16.32	41.00	19–76	7.63	$P < .0001$	1.71
HBI follow-up	51.20	17.69	53.50	19–80	5.82	$P < .0001$	1.30
SCS baseline	31.90	4.97	32.00	23–40			
SCS mid treatment	23.90	9.10	25.00	10–40	4.80	$P < .0001$	1.07
SCS end of treatment	20.25	7.32	18.50	10–39	7.90	$P < .0001$	1.77
SCS follow-up	25.60	7.40	25.50	13–39	4.63	$P < .0001$	1.03

HD: CAS = Hypersexual Disorder: Current Assessment Scale; HBI = the Hypersexual Behavior Inventory; SCS = the Sexual Compulsivity Scale. Mid treatment = 2 weeks with naltrexone; end of treatment = 4 weeks with naltrexone; follow-up = 4 weeks without naltrexone.
*compared to baseline measures.

Figure 3. Changes in HD: CAS mean score from baseline to week 8 in men (n = 20) with CSBD. HD: CAS = Hypersexual Disorder: Current Assessment Scale.

Interestingly, the decrease on HD: CAS scores during the pharmacological therapy corresponds to the decrease after cognitive behavioral therapy group intervention for HD reported in the feasibility study by Hallberg et al[34] Without doubt, there is a need for studies comparing psychotherapy and pharmacotherapy in CSBD. Meanwhile, as psychotherapy is not always suitable or accessible, treatment with naltrexone might be a useful addition to be taken into consideration if shown efficacious in randomized controlled trial studies.

As presented in Figure 2, a few participants did not show any distinct decline in HD: CAS. Notably, higher doses of naltrexone have previously been reported more effective in both forensic and nonforensic samples.[13,14] However, in Sweden, the recommended dosage to treat alcohol dependence is 50 mg/day. Being the first study on naltrexone on the indication of CSBD conducted in Sweden, the recommended dosage was not exceeded. Nonetheless, it would have been of interest to augment the dosage of the nonresponders or further investigate subgroups in terms of clinical characteristics. Nevertheless, the cohort is too small for subanalysis and future studies should therefore ensure a larger sample.

Most participants were considered to either fulfil the criteria for a history of or a current psychiatric diagnosis, predominately anxiety and affective disorders, in congruence with previous reports on comorbidity in CSBD.[46–48] Furthermore, the participants reported high levels of anxiety at baseline. Altogether, it highlights the need to assess for coexisting conditions in persons with CSBD.

Strengths of the present study include the accurate diagnostic process in a subspecialized sexual medicine unit with vast experience in evaluating sexual behaviors, the use of validated measures, and several assessments without missing data. It has been reported that methodological limitations such as small sample sizes, participants being exclusively men, and discrepancies in inclusion criteria are making it difficult to draw conclusions from existing pharmacological studies.[49] Hopefully, the strengths of the study will add some insights to the treatment of CSBD.

Some limitations of the study must be discussed. First, the study format was an open study without a control group; therefore, the decrease on HD: CAS and HBI could simply arise from the fact of being under any kind of treatment and highlighting problematic sexual behaviors. Thus, conclusions on the effectiveness of naltrexone cannot be made. Second, the used questionnaires have not been validated in Swedish; however, they have been used in Swedish research before this study. Moreover, participants with severe ongoing depression and substance abuse were excluded. As noted previously, comorbidity is common in CSBD, and future studies should include participants with and without comorbidity in a randomized procedure.

Another limitation was the relatively short treatment and follow-up period. Being a pilot study, the specific time span was chosen to enhance the premise to evaluate tolerability and to perceive indication of possible benefits of naltrexone. Furthermore, the reports of compliance may not be fully reliable. Despite pill count and questions on adherence, other measures could have been considered such as analysis of urine samples for the active metabolite of naltrexone, as well as the use of ecological momentary assessment such as a smartphone app with daily reports.Finally, despite the fact that the study was open for both men and women, no women signed up for participation. Possible explanations include the fact of CSBD being less common in women,[50] or participation was simply not considered attractive. Future studies should try to find ways to include women.

CONCLUSION

The present prospective pilot study provides novel insights on a pharmacological intervention in men with CSBD. The results suggest that naltrexone is feasible, tolerable, and may reduce symptoms of CSBD. Nevertheless, to evaluate possible effectiveness, future studies should ensure larger samples, the use of randomized controlled procedure, accurate measures on compliance, longer treatment periods, include women, and participants with different sexual orientations.

Corresponding Author: Josephine Savard, MD, Department of Clinical Sciences/Psychiatry, Umeå University, Umeå, Sweden. Tel: +46851773200; Fax: +46851771814; E-mail: josephine.savard@umu.se

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STATEMENT OF AUTHORSHIP

Category 1

(a) Conception and Design
Josephine Savard; Katarina Görts Öberg; Andreas Chatzittofis; Cecilia Dhejne; Stefan Arver; Jussi Jokinen

(b) Acquisition of Data
Josephine Savard; Katarina Görts Öberg; Cecilia Dhejne; Stefan Arver; Jussi Jokinen

(c) Analysis and Interpretation of Data
Josephine Savard; Jussi Jokinen

Category 2

(a) Drafting the Article
Josephine Savard; Jussi Jokinen

(b) Revising It for Intellectual Content
Josephine Savard; Katarina Görts Öberg; Andreas Chatzittofis; Cecilia Dhejne; Stefan Arver; Jussi Jokinen

Category 3

(a) Final Approval of the Completed Article
Josephine Savard; Katarina Görts Öberg; Andreas Chatzittofis; Cecilia Dhejne; Stefan Arver; Jussi Jokinen

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SUPPLEMENTARY DATA

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jsxm.2020.04.318.