ment, loss of empathy, withdrawal and insularity, and impaired work performance, as well as several anxiety, depression and irritability symptoms which are viewed as common burnout concomitants. The consistency across the BAT model, the SBM construct and descriptions of acedia argues for the validity of such a broader conceptualization of burnout and for a potentially meaningful set of operational criteria.

Another issue is that of context specificity, with burnout long viewed as a work-related phenomenon and with "work" restricted to formal/paid employment. It has been argued[2] that, if burnout's work-specific context were removed, two of the promulgated symptoms (i.e., depersonalization/cynicism at work, and reduced professional efficacy) would become irrelevant and reduce burnout's definition to exhaustion only. Clinically, however, we observe burnout in individuals not formally employed (e.g., parents looking after children with disabilities, or people caring for elderly relatives with high demands), while others have argued that "work" in the context of burnout should be viewed more broadly[6]. Thus, the context specificity concern is a straw man argument.

A further key argument[2] has been that burnout is actually depression (and thus is already classified). Whether burnout is or not synonymous with depression has long been debated[8]. A recent meta-analysis[9] of 69 studies reported an overall correlation of r=0.52 between burnout and depression, concluding that the two conditions, although sharing some features, are "different and robust constructs". Indeed, although anxiety and depression correlate moderately to highly, this does not mean that they are synonymous, and diagnostic manuals have long listed separate categories of depressive and anxiety disorders. We argue for viewing the relationship between burnout and depression similarly.

We now consider how burnout might be diagnosed as a mental disorder, respecting the need for a set of criteria/requirements in accord with DSM and ICD models.

We suggest a criterion A requiring a work-based stressor, but allowing that it may occur in formal (i.e., paid) or informal (i.e., unpaid) "work" environments: "The individual has been exposed to excessive formal or informal work demands, that are generally in the form of excessive workload pressures but can also reflect physical environment, work inequity, role conflict or unfair treatment factors".

A criterion B would list five symptoms (generated in empirical studies noted earlier): a) exhaustion (i.e., lack of energy across the day, lethargy, fatigue, waking up feeling tired); b) cognitive disturbance (i.e., concentration is foggy, attention less focused, material needs to be re-read); c) loss of feeling in work or outside of work (the individual feels disengaged, less empathic, and experiences a loss of *joie de vivre*); d) insularity (e.g., tendency to avoid others and to socialize less, deriving less pleasure from social interaction); e) compromised work performance (e.g., less driven to meet work responsibilities, contributing less at work, finding little things and chores frustrating, quality of work compromised in general and/or by making mistakes). To reduce the risk of over-diagnosis, we suggest that all five symptoms should be present.

A criterion C would require (in line with the DSM and ICD) that the symptoms cause clinically significant distress or impairment in social, occupational or other important areas of functioning.

A criterion D ("not caused by a medical condition or by the physiological effects of a drug or medication") is important to impose, as individuals may score high on burnout measures and meet the criterion B as a consequence of a range of other psychological conditions (e.g., depression), medical conditions (e.g., severe anaemia, post-COVID state), treatments (e.g., chemotherapy) or the effects of certain drugs.

In conclusion, we believe that reasons for not listing burnout as a clinical condition can be countered, and offer candidate criteria for consideration, thus making a case for its formal inclusion in classification systems.

Gordon Parker, Gabriela Tavella
Discipline of Psychiatry and Mental Health, School of Clinical Medicine, University of New South Wales, Sydney, NSW, Australia

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DOI:10.1002/wps.21025

Tolerability and efficacy of paroxetine and naltrexone for treatment of compulsive sexual behaviour disorder

Compulsive sexual behaviour disorder (CSBD) has recently been introduced in the ICD-11. However, despite increasing research on its psychological and neural mechanisms, little is known about the efficacy of pharmacotherapy in people with this condition[1].

To date, only some case reports and one small (28 males) randomized controlled trial (RCT) have provided some evidence for the efficacy of selective serotonin reuptake inhibitors (SSRIs) in the reduction of sexual compulsivity[2]. Several case studies and one small (20 males) open-label study reported the clinical usefulness of the opioid antagonist naltrexone in CSBD[3]. Most studies were conducted before CSBD diagnostic guidelines were

proposed in 2019.

We aimed to assess the safety and efficacy of an SSRI (paroxetine) and of naltrexone in male patients seeking treatment at an outpatient sexology clinic who met the ICD-11 diagnostic guidelines for CSBD. For this purpose, we conducted a 20-week double-blind and placebo-controlled RCT, approved by the local ethics review board in accordance with the Declaration of Helsinki.

Among the 73 recruited heterosexual cisgender men (mean age: 35.7±8.1 years), 24 were randomly assigned to paroxetine (20 mg/day), 24 to naltrexone (50 mg/day), and 25 to the placebo condition. No significant group differences were observed with respect to CSBD symptoms or demographic characteristics prior to treatment.

Results from the trial confirmed that paroxetine and naltrexone represent safe treatment options for CSBD. The total discontinuation rate was 15.1%, with the following causes for stopping medication: adverse effects (five patients, 6.8%: two with paroxetine, three with naltrexone); lack of improvement or worsening of CSBD symptoms (two patients, 2.7%, both with placebo); irregular medication intake (one patient, paroxetine group). Three patients (4.1%) discontinued/failed to show up at follow-up (two in paroxetine and one in naltrexone group). No difference in treatment non-adherence was noted between groups ($F_{2,57}$=0.25, p=0.78).

The most bothersome and persistent side effects included sedation (29.2% with paroxetine, 37.5% with naltrexone, and 0% with placebo), apathy (8.3%, 8.3% and 0%, respectively), orgasmic dysfunction (2.8%, 0% and 0%, respectively), erectile dysfunction (12.5%, 0% and 8%, respectively), and weight gain (16.7%, 4.2% and 12%, respectively). No medication-related serious side effects occurred during the trial.

We observed a significant effect of time on severity of CSBD symptoms using self-report questionnaires: Hypersexual Behavior Inventory ($F_{1,55}$=83.59, p<0.001, η^2=0.60), Brief Pornography Screen ($F_{1,47}$=34.66, p<0.001, η^2=0.42) and Sexual Addiction Screening Test ($F_{1,47}$=17.06, p<0.001, η^2=0.27). However, there was no difference between the conditions at any time point, nor an interaction of time and condition. Self-reported frequency of pornography consumption ($F_{1,57}$=28.69, p<0.001, η^2=0.34) and duration of pornography consumption ($F_{1,52}$=7.863, p<0.01, η^2=0.13) decreased over the time of treatment across all conditions. No condition or interaction (time x condition) effects were noted.

On the other hand, clinical interviews revealed that patients treated with paroxetine or naltrexone, compared to placebo, were more likely to achieve at least 30 days of cessation of any compulsive sexual behaviour at treatment week 8 (X^2=7.097, p=0.029, Cramer's V=0.34); to have a reduced frequency of sexual binges at week 20 (X^2=6.935, p=0.031, Cramer's V=0.34); and to have a decrease in frequency of CSBD symptoms at both time points (week 8: X^2=12.250, p=0.016, Cramer's V=0.31; week 20: x^2=8.208, p=0.017, Cramer's V=0.37). They also reported higher satisfaction with treatment effects at both time points (week 8: X^2=15.801, p=0.003, Cramer's V=0.35; week 20: X^2=1.886, p=0.018, Cramer's V=0.31).

Using smartphone-administered daily ecological momentary assessment (EMA), we observed a significant interaction (time x condition) effect in craving for sexual activity ($F_{6,1011.57}$=3.12, p=0.005). Patients receiving paroxetine reported significantly less craving for sexual encounters in the last week of treatment (estimated marginal means, EMMs=3.71, SE=0.55) compared to baseline (EMMs=4.88, SE=0.48) (c=1.17, lower control limit, LCL=0.07, upper control limit, UCL=2.27, p=0.03). A significant interaction (time x condition) effect was also found in craving for pornography viewing ($F_{6,1020.12}$=2.54, p=0.002). Craving for pornography in the 20th week of treatment with paroxetine (EMMs=2.69, SE=0.48) was significantly lower compared to baseline (EMMs=3.97, SE=0.39) (c=1.28, LCL=0.07, UCL=2.49, p=0.03).

To summarize, our double-blind placebo-controlled RCT demonstrated that paroxetine and naltrexone are safe and well-tolerated by men with CSBD. Patients usually reported mild and transient side effects with either medication, and most complaints were similar to reports on safety and tolerability profiles of paroxetine and naltrexone in their registered indications, except for a high incidence of sedation reported by naltrexone users. A 6.8% discontinuation rate due to adverse effects is relatively low compared to other studies[4,5].

Based on clinical interviews, both medications were found to be more effective than placebo in reducing CSBD symptoms. Such a superiority of both active treatment arms over placebo was visible at the 20th week, but as early as the 8th week. EMA provided support for higher effectiveness in reducing craving for sexual encounters and pornography viewing in the paroxetine condition. However, based on data from self-report questionnaires and self-reported pornography consumption, the superiority of paroxetine and naltrexone over placebo did not reach statistical significance. Therefore, the clinical efficacy of these drugs in CSBD should be confirmed by further studies.

The high effectiveness of placebo in CSBD may be related to such factors as disclosing the problem, motivation for change, and initiation of therapy while receiving external support from the study team. Prior research[6] has also demonstrated high placebo response rates in gambling disorder treatment. Such results warrant further attention to non-specific factors related to therapy as meaningful for clinical improvement in CSBD.

Michał Lew-Starowicz[1], Małgorzata Draps[2], Ewelina Kowalewska[1], Katarzyna Obarska[2], Shane W. Kraus[3], Mateusz Gola[2,4]

[1]Department of Psychiatry, Centre of Postgraduate Medical Education, Warsaw, Poland; [2]Institute of Psychology, Polish Academy of Sciences, Warsaw, Poland; [3]Department of Psychology, University of Nevada, Las Vegas, NV, USA; [4]Swartz Center for Computational Neuroscience, Institute for Neural Computations, University of California San Diego, San Diego, CA, USA

Supplementary information on the study is available at https://osf.io/zexm4.

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DOI:10.1002/wps.21026