AKADÉMIAI KIADÓ

Journal of Behavioral Addictions

12 (2023) 1, 261–277

DOI:
10.1556/2006.2023.00004

FULL-LENGTH REPORT

Treatment effects and adherence of sexually compulsive men in a randomized controlled trial of psychotherapy and medication

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Received: August 31, 2022 • Revised manuscript received: January 12, 2023; January 27, 2023 • Accepted: February 3, 2023
Published online: March 9, 2023

ABSTRACT

Background: Little attention has been given to efficacious treatment and adherence to treatment of compulsive sexual behavior (CSB). *Aims:* Randomized controlled trial investigated short-term psychodynamic group therapy followed by relapse prevention group (STPGP-RPGT) and pharmacological treatment (PT) for CSB men on sexual compulsivity and adherence. *Method:* 135 men, 38 (SD = 9) years old on average, were randomly assigned to 1) STPGP-RPGT; 2) PT; 3) Both. Participants completed measures at baseline, 25th, and 34th week. 57 (42.2%) participants dropped out between baseline and 25th week, and 68 (50.4%) between baseline and 34th week. 94 (69.6%) did not adhere (80% pills taken or attended 75% therapy sessions). *Results:* A significant interaction effect was found between time and group (F (4, 128) = 2.62, P = 0.038, ES = 0.08), showing who received PT improved less in sexual compulsivity than those who received STPGP-RPGT (t = 2.41; P = 0.038; ES = 0.60) and PT + STPGP-RPGT (t = 3.15; P = 0.007, ES = 0.74). Adherent participants improved more in sexual compulsivity than non-adherent at the 25th week (t = 2.82; P = 0.006, ES = 0.65) and 34th week (t = 2.26; P = 0.027, ES = 0.55), but there was no interaction effect, F (2, 130) = 2.88; P = 0.06; ES = 0.04). The most reported behavior (masturbation) showed greater risk of non-adherence (72.6%). *Discussion and conclusions:* Adherent participants improved better than non-adherent. Participants who received psychotherapy improved better than those who received PT. Methodological limitations preclude conclusions on efficacy.

KEYWORDS

compulsive sexual behavior, randomized clinical trial, group psychotherapy, treatment effects, psychodynamic

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INTRODUCTION

Compulsive sexual behavior disorder (CSBD) is characterized by the inability to control intense, repetitive sexual impulses resulting in repetitive sexual behavior over an extended period. It causes marked distress or significant impairment in personal, family, social, educational, occupational, or other important areas of functioning (Kraus et al., 2018; World Health Organization, 2018). This definition highlights the severe negative consequences associated with CSBD, which are increased by the significant proportion of psychiatric comorbidities, like impulsivity and addiction disorders, resulting in decreased adherence to treatment, high rates of treatment discontinuation, and global impairment in life (Briken, 2020).

Before the inclusion of CSBD criteria in ICD-11, there was a massive body of knowledge wherein different names were used, such as sexual addiction, excessive sexual drive, and hypersexual disorder. In the same way as Grubbs, Hoagland et al. (2020), we will mention compulsive sexual behavior (CSB) in this paper to refer to all non-paraphilic out-of-control or dysregulated sexual behavior patterns, although we recognize the conceptual differences between those terminologies.

The low rate of retention of people seeking treatment for impulse control disorders (Mallorquí-Bagué et al., 2018) is an important limitation of the field, compromising the ability to estimate treatment effects. This study aimed to address this empirical gap. Unfortunately, the efficacy of treatments for CSB is also limited due to many methodological limitations in the current literature, which is very concerning considering the estimated prevalence of CSB in men. In Hungary, 5% of men scored above critical scores on the Compulsive Sexual Behavior Disorder Inventory – 19 (Böthe et al., 2020). In Poland, 8.7% of men report some agreement with pornography addiction (Lewczuk, Glica, Nowakowska, Gola, & Grubbs, 2020), as in 4.4% of Australian men (Rissel et al., 2017). Also, four surveys in the United States showed prevalences between 5.4% and 18.3% of men who reported feelings of difficulty control over sexual behavior or some agreement with pornography addiction (Dickenson, Gleason, Coleman, & Miner, 2018; Grubbs, Grant, & Engelman, 2018; Grubbs, Hoagland, et al., 2020; Grubbs, Kraus, & Perry, 2019; Grubbs, Lee, Hoagland, Kraus, & Perry, 2020). The first probabilistic prevalence study by Briken et al. (2022) showed that 4.9% of german-speaking men reported experiences consistent with the ICD-11 requirement for CSBD diagnosis.

Despite the critical prevalence, treatment studies are mostly retrospective or single-group designs, have small sample sizes, short follow-up periods, use non-validated measures, and do not use structured clinical interviews (Hook, Reid, Penberthy, Davis, & Jennings, 2014; von Franqué, Klein, & Briken, 2015). There are a few exceptions, such as one RCT comparing group-administered cognitive behavioral therapy (CBT) with a waiting list (Hallberg et al., 2019) and three studies that have included a proper comparative control condition (Lew-Starowicz et al., 2022; Wainberg et al., 2006; Wilson, 2010).

Efrati and Gola (2018) have identified some promising intervention studies for CSB using cognitive-behavioral therapy, cognitive-analytic therapy, mindfulness, and self-help groups. However, methodological limitations and a need for more efficacious findings continue to hold back the full implementation of these theoretical approaches (Efrati & Gola, 2018; Hook et al., 2014).

A new systematic review found that receiving treatment seems to improve symptoms of CSB, and the first evidence is in favor of CBT (Antons et al., 2022). However, the knowledge regarding effective pharmacologic and psychotherapy treatments for CSB remains sparse regarding how they impact the main symptomatology and the negative consequences (Briken, 2020; Lew-Starowicz, Lewczuk, Nowakowska, Kraus, & Gola, 2020).

Accordingly, psychodynamic therapy has been found to be efficacious in clinical settings in improving emotional and impulsive dysregulation, which are characteristics of CSB, considering mentalization-based treatment (Bateman & Fonagy, 2010; Fonagy, 2015), transference-focused therapy and short psychodynamic therapy (Levy et al., 2006). It may be suitable to address the high prevalence of chronic childhood and adolescence stress conditions among CSB individuals (Blain, Muench, Morgenstern, & Parsons, 2012; Kingston, Graham, & Knight, 2017) because psychodynamic approaches consider the influence of psychic conflicts related to challenging childhood or adolescence experiences for maintenance of adulthood symptoms (Blagys & Hilsenroth, 2006; Shedler, 2010). It encourages patients to express their emotions and conditions to explore their relations with symptoms to reduce them and improve their quality of life (Blagys & Hilsenroth, 2006; Shedler, 2010). Furthermore, psychodynamic group psychotherapy shows effectiveness in treating psychiatric conditions with similar symptoms, like personality disorders (Jensen, Mortensen, & Lotz, 2010; Levy et al., 2006). Two pilot studies using short-term psychodynamic therapy have been conducted with good results.

The first pilot involved two severe CSB individuals who reported among 30 – 50 casual partners in the last six months with risky sexual practices (Amaral & Scanavino, 2012). The second pilot involved five CSB men with diverse sexual identities (Scanavino, Kimura, Messina, Abdo, & Tavares, 2013). All participants underwent short-term psychodynamic therapy and received prescribed medication (two patients took sertraline; one patient took paroxetine and naltrexone; one patient took topiramate; one patient took paroxetine and topiramate; one patient took sertraline, topiramate, and clonazepam; one patient took paroxetine and lamotrigine). The first was delivered individually, while the second was in a group format. Except for one participant who did not finish the group therapy, all participants scored above the risk threshold on the Sexual Compulsivity Scale, SCS (Scanavino et al., 2016) and reduced their scores to below the cut-off after treatment. These initial studies provide preliminary support for the potential efficacy of psychodynamic therapy associated with prescribing medication, mostly SSRIs and mood stabilizers, in CSB.

The classes of medication that show the most potential to regulate CSB are selective serotonin re-uptake inhibitors (SSRI) (e.g., citalopram), which negatively influence erectile function and sexual desire and help treat associated comorbid symptoms or disorders (Briken, 2020; Grant & Potenza, 2004; Lew-Starowics et al., 2022); mood stabilizers, and anticonvulsants (e.g., topiramate) (Khazaal & Zullino, 2006), used to reduce impulsivity (Jones et al., 2011), mood associated-behavior (Grant & Potenza, 2004) and addicted-associated behavior (de Britto et al., 2017); opioid antagonists (e.g., naltrexone) used to reduce addictive symptoms (Raymond, Grant, Kim, & Coleman, 2002; Savard et al., 2020; Lew-Starowics et al., 2022); and anti-androgenic drugs used to treat hypersexual symptoms and sexual urges (e.g., medroxyprogesterone acetate) (Winder et al., 2018). However, there is no strong evidence of the superiority of effectiveness between medication or drug classes over the others (Leppink & Grant, 2016), with a few exceptions, such as a recent double-blind RCT comparing paroxetine, naltrexone, and placebo for CSB patients. There was no difference between treatment modalities according to standardized measures on sexual compulsivity or hypersexuality. However, clinical records showed that both medications reduced CSB symptoms more than the placebo. Also, using smartphone-administered daily ecological momentary assessment (EMA), the authors observed that paroxetine reduced craving for sexual encounters and pornography viewing more than naltrexone and placebo (Lew-Starowics et al., 2022).

Given the literature supports the combination of psychosocial interventions, particularly for highly comorbid patients (Carandang et al., 2020; Crits-Christoph et al., 1999; Orzack, Voluse, Wolf, & Hennen, 2006) and the severity of relapse in CSBD (Zawacki, Stoner, & George, 2005), a relapse prevention group therapy (RPGT) was added to the short-term psychodynamic group psychotherapy (STPGP). A randomized controlled trial (RCT) was conducted to investigate the effects of (1) STPGP-RPGT, (2) pharmacological treatment (PT), and (3) a combination of both interventions on sexual compulsivity and adherence to treatment.

Based on the pilot studies which showed the potential efficacy of psychodynamic therapy associated with prescribing medication in CSB, we hypothesize that pharmacological and psychotherapy resulted in a greater effect than isolated modalities. Moreover, we hypothesized that psychotherapy likely was responsible for a greater effect than pharmacotherapy in those pilot studies since there is initial evidence of the effect of psychotherapy on the waiting lists when investigating through standardized CSB measures (Hallberg et al., 2019), while two RCT comparing medication and placebo did not find differences on the standardized measures (Lew-Starowics et al., 2022; Wainberg et al., 2006).

The STPGP relies upon psychodynamic psychotherapy principles, like therapeutic alliance, relations of familiar transference issues with symptoms, and learning with experienced emotions (Lowenkron, 2008). In a group context, the therapy allows patients to foster group cohesion, disclosure, social identity, and empathy as mechanisms of change (Burlingame, Fuhriman, & Mosier, 2003). The STPGP has goals of psychoeducation of compulsive sexual behavior, increasing control of compulsivity, reduction of anxiety and depression, improving the decision-making of sexually compulsive behaviors, and a better understanding of symptoms related to psychodynamic relationships based on similar processes of psychodynamic group psychotherapy (Bechelli & Santos, 2006; Vinogradov & Yalom, 1989).

METHOD

Participants

The study occurred at the Excessive Sexual Drive and Prevention of Negative Outcomes associated to Sexual Behavior Unit of the Institute of Psychiatry of the Hospital das Clínicas da Faculdade de Medicina da Universidade de Sao Paulo, a large tertiary hospital in a Brazilian metropolis. The unit provides treatment and is demanded by many treatment seekers for CSB. Therefore, no active recruitment strategy was necessary for this study as we could screen participants who naturally sought treatment.

All participants met the criteria for the excessive sexual drive (International Classification of Diseases – ICD-10 F52.7) and Goodman's Criteria (Goodman, 2001). The criteria of excessive sexual drive (International Classification of Diseases – ICD-10 F52.7) were investigated through the following questions and statements: "why did you come to the outpatient clinic;" "describe your sexual behavior;" "why do you believe your sexual behavior is excessive;" "describe situations where you have lost control over your sexual behavior." Those who reported excessive sexual behavior consistently for at least six months and reported frequent situations of losing control over the sexual behavior were considered to have excessive sexual drive. Goodman's criteria are an adaptation of the DSM-IV substance dependence to CSB and define it as the occurrence of repetitive problematic sexual behavior leading to clinically significant impairments in 12 months with three or more of the following symptoms: tolerance, withdrawal, frequent sexual behavior, that continues despite negative outcomes, unsuccessful efforts to control it, considerable time spent in preparation for it, social or occupational activities diminishing.

Participants with 18 years or older, meeting criteria for gender identity (ICD-10 F64), sexual preference (ICD-10 F65), current bipolar (ICD-10 F30.0, F31.0, 31.1, and 31.2), schizophrenia (ICD-10 F20) or other mental disorders due to brain dysfunction, injury, or physical disease (ICD-10 F06) were excluded.

Four trained psychiatrists in the assessment and treatment of CSB conducted clinical interviews to assess clinical criteria and ICD-10 conditions.

Of the 254 individuals assessed from February 2011 to July 2014, 119 were not eligible to participate (Fig. 1) because they did not meet diagnosis criteria ($n = 22$), did not appear for further evaluations, and also did not give reasons to stop participating the study ($n = 74$), and lived outside the city ($n = 23$). The final sample consisted of 135

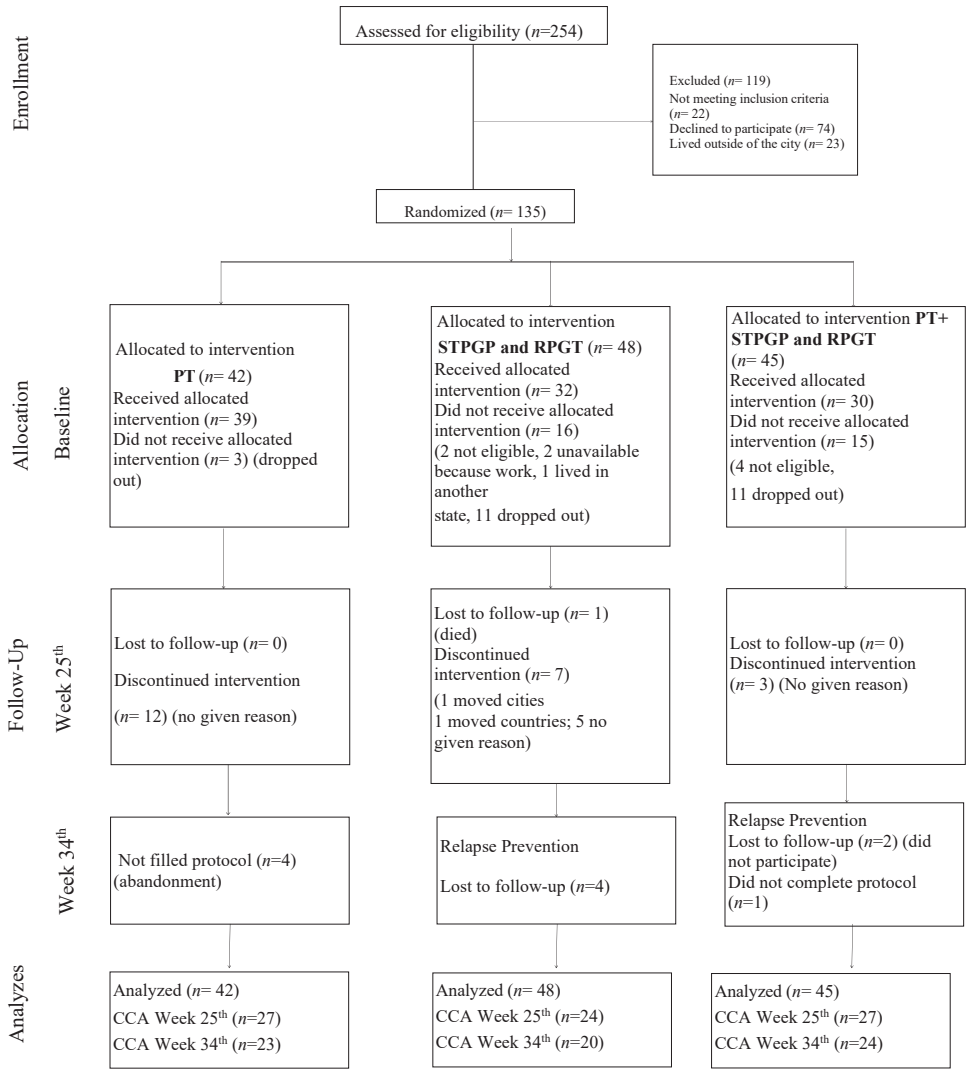

Fig. 1. Flowchart of the study

Note: PT = Pharmacological Treatment (psychiatric follow up with prescribed medication); STPGP = Short-Term Psychodynamic Group Psychotherapy; RPGT = Relapse Prevention Group Therapy; CCA = Complete Case Analysis.

Portuguese-speaking men 18 years or older who met Goodman's criteria and excessive sexual drive.

The participants' age ranged between 23 and 67 years old. 45.9% self-reported as gay or bisexual, 60.7% were married or living in a stable union, 72.6% self-reported as white, and 82.2% completed at least high school.

No participant received financial compensation for participation in the study.

Measures

Sociodemographic characteristics. Participants self-reported their age, marital status, ethnicity, education, employment status, monthly income, and sexual orientation.

Medical records. The doctors and psychologists registered the presence of therapy sessions, medication adherence, side effects, CSB-related symptoms, and negative outcomes in the medical records.

Hospital pharmacy electronic system. It is an electronic registration of the medication delivered to the outpatients. Those who took the medication in the hospital pharmacy had the adherence estimated based on the rate of refill of the medication registration.

Problematic sexual behaviors. Participants self-reported their engagement in compulsive masturbation, compulsive use of pornography, excessive casual sex, and whether they had multiple casual sexual partners. Items were rated on a Yes/No scale.

Primary outcome. Participants completed the Brazilian version of the SCS, a 10-item self-report scale (e.g., My sexual thoughts and behaviors are causing problems in my life) with Cronbach's alpha of 0.95 (Scanavino et al., 2016), while in the present study was 0.89. Items are from 1 (not at all like me) to 4 (very much like me) and summed to provide a total score. The scores range from 10 to 40, with higher scores representing greater sexual compulsivity (Kalichman

& Rompa, 1995). It is a uni-dimensional measure to evaluate repetitive sexual thoughts and behavior trends with strong psychometric properties in different samples (Hook, Hook, Davis, Worthington, & Penberthy, 2010).

Procedure

Upon completion of baseline assessments, which consisted of a clinician-administered psychiatric assessment for eligibility criteria, sociodemographic aspects, problematic sexual behaviors, and sexual compulsivity, participants were allocated to an assigned treatment arm according to randomization. They were also assessed for sexual compulsivity at the 25th and 34th week from the onset of the study (Fig. 1).

The present RCT used a pretest-posttest parallel control group design.

STPGP. Participants randomized to STPGP completed four to six individual psychological sessions designed to (1) investigate willingness to participate in group therapy, (2) assess feasibility for participants, (3) identify whether they were not currently in treatment, and (4) apply the Sifneos selection criteria (motivation to undergo) for brief dynamic psychotherapy – modified version (Høglend, Sørbye, Sørlie, Fossum, & Engelstad, 1992). If participants responded "Yes" to the first three items and were good candidates according to Sifneos criteria, they were determined to be eligible for STPGP. Two participants assigned to psychotherapeutic treatment and four to the combined intervention were not eligible for STPGP. They did not attend psychotherapy sessions but were kept in the treatment modality that was allocated for initial statistical purposes. The STPGP was delivered by a psychotherapist with experience conducting STPGP for CSB patients. A research assistant was present to register all sessions. The STPGP was conducted through 16 weekly sessions of 90 min. The composition of the groups ranged from seven to ten participants. In the first group session, group norms are discussed (e.g., not contacting participants outside of therapy). After the first session, the group management follows the psychodynamic group psychotherapy rationale of the therapist as a mediator of the patient, managing discussion sessions (Bechelli & Santos, 2006). The therapist's role during STPGP treatment actively encourages dialogue between participants, highlights the patient's focus on the connections between CSB and internal psychic conflicts, fosters associations between early life problematic experiences and genesis and maintenance of CSB, attends to group dynamics, favors developing group cohesion, exposes resistance to the psychotherapeutic process, points out and interprets defense mechanisms, as well as transference, provides information and education about CSB and the psychotherapeutic process and develops supportive interventions. The STPGP also followed goals of psychoeducation of compulsive sexual behavior, increasing control of compulsivity, reduction of anxiety and depression, stimulating relations with symptoms, and psychodynamic relationships throughout sessions. An STPGP guide for CSB is present in the supplementary material.

The overview of the sessions was conducted in group meetings with five psychologists and psychiatrists from the team, who drafted the main concepts of the guide. The median number of group sessions attended by participants was nine 95% CIs [0, 16] in the STPGP-RPGT group and nine 95% CIs [0, 15] in PT + STPGP-RPGT group.

RPGT. The RPGT is an eight-week therapy group lasting 90 min, conducted by three psychologists from the team. The sessions were based on relapse prevention theory (Hendershot, Witkiewitz, George, & Marlatt, 2011; Witkiewitz & Marlatt, 2004). The first session discussed the theory of relapse prevention. The second focused on the psychoeducational approach to CSB. The third provided the skills to participants to track and monitor their sexual desires, triggering factors, internal dialog, and reflect on the consequences of CSB. The fourth involved psychoeducational support on preventing HIV and STI sexual risk behaviors. The fifth and sixth sessions involved skills training to manage high-risk situations. The final two sessions involved problem-solving to overcome difficulties shown in the previous sessions. The median number of group sessions attended by participants was four and a half, 95% CIs [0, 8] in the STPGP-RPGT group and five, 95% CIs [0, 8] in the PT + STPGP-RPGT.

PT. Initially, three visits were conducted at intervals of 30 days. Thereafter follow-ups occurred at 60-day intervals. The medication protocol included SSRI (fluoxetine, paroxetine, or sertraline) delivered alone or combined with mood stabilizers (topiramate, divalproex sodium, oxcarbazepine, or lamotrigine) or mood stabilizers prescribed alone in the usual dosages used to depression or mood disorder. Participants reporting mostly sexually compulsive symptoms received SSRIs (Briken, 2020; Grant & Potenza, 2004), while participants reporting also impulsive symptoms had the prescription augmented of mood stabilizers (Grant & Potenza, 2004; Jones et al., 2011)). Participants reporting mostly impulsive symptoms received just mood stabilizers (Jones et al., 2011). Four trained psychiatrists conducted follow-up visits to assess CSB-related symptoms, negative outcomes, the presence of side effects, and medication adherence with participants. Research team meetings were held to resolve discrepancies and discuss participant concerns. The psychiatrists discussed the participants' clinical follow-up based on excessive sexual drive and Goodman's criteria. Those meetings helped to overcome potential discrepancies in the clinical evaluation among the psychiatrists.

The median number of visits to the psychiatrists was five, 95% CIs [1, 7].

Most (97.7%) of the patients in PT were prescribed an SSRI. Of these, 20.7% were also prescribed a mood stabilizer. 2.3% of participants were prescribed only a mood stabilizer. The participants, on average, took 65.4%, 95% CIs [16.8 – 100%] of medications prescribed, which was calculated based on the rate of refill of the medication registered in the hospital pharmacy electronic system for 66 (75.9%) of the participants who decided to pick the medication up in the

hospital pharmacy for free. However, 21 participants decided to buy the medications at a private pharmacy. In these cases, based on Coldham, Addington, and Addington (2002), we classify adherence to medication into two categories: 1) non-adherent (medication was used erratically or not used); 2) adherent (doses were rarely or never omitted). According to the medical records, most (95.2%) patients who bought medications at private pharmacies were not-adherent.

Adherence to STPGP protocol. Three raters assessed the therapist's adherence to the STPGP guide after reading the research assistant's registry of four sessions (2nd, 4th, 12th, and 14th) of the group. The sessions and the group were randomly selected from the total number of sessions, and the whole therapy group was conducted (8). The form comprises 17 items investigating the therapist's fidelity to the STPGP guide. The raters classified the 17 items of the therapist's performance according to the following scale (0 = does not apply, 1 = no adherence; 2 = low adherence; 3 = good adherence; 4 = total adherence). The average rating was 3.48 (SD = 0.46), suggesting high fidelity to the protocol. All raters classified the 17 items at least as "good adherence," and two raters classified at least 11 items as presenting "total adherence."

Adherence to RPGT protocol. Three psychologists worked in pairs to conduct the groups. They provided a descriptive report of each step of the group sessions. A six-item form for rating the therapist's adherence was completed. The first four items assessed sessions one to four, while the last two items assessed, respectively, sessions five and six and seven and eight. Three external raters, psychologists with expertise in psychotherapy, classified the therapist's adherence to the RPGT protocol, answering the six items based on the following scale (0 = does not apply, 1 = any adherence; 2 = low adherence; 3 = good adherence; 4 = total adherence). The average rating for the entire protocol was 2.98 (SD = 0.52), suggesting good fidelity to the protocol.

Adherence to PT. Medication adherence was assessed retrospectively through medical records. A research assistant systematically reviewed the medical charts to assess the adherence of the psychiatrists to the PT protocol. The physicians presented a good adherence (checked out at least 75% of the topics of the PT protocol) consistently according to the protocol.

Statistical analysis

The data was analyzed by JASP v1.14 statistical software. Differences among groups were described with ANOVA for normal continuous variables and Kruskal Wallis for non-normal continuous variables. Chi-squared tests were performed to compare frequencies for qualitative variables between group treatments. The ANOVA one and two way for repeated measures was conducted for time effect study and between-group comparison changes of SCS scores over time in PT, PT + STPGP-RPGT, and STPGP-RPGT groups in baseline, 25th week, and 34th week. Holm post hoc test was used to adjust the p-value for multiple comparison tests. Paired sample T-tests and nonparametric alternative Mann-Whitney U test were measured for adherence group comparison. A multinomial test was performed to compare the proportion of problematic behaviors across groups. Conditional Bayes probability (P (A/B) = P (A∩B)/P(B) were assembled to calculate the relative risk of non-adherence in the presence of one or several problematic behaviors simultaneously (Depaoli, Rus, Clifton, van de Schoot, & Tiemensma, 2017). The statistical significance was set at 5%.

The sample size was estimated using the concept of minimum detectable clinical difference (Mouelhi, Jouve, Castelli, & Gentile, 2020) - since we do not have previous data in the literature and follow clinical impressions. Psychotherapy brings more skills to deal with the problems in the medium and long term, even when the treatment ends, while PT is more related to the effect that finishes when the medication is suspended (Cuijpers, Reijnders, & Huibers, 2019; McAleavey & Castonway, 2015). Therefore, considering a 34-week treatment, we hypothesized that those participants attending psychotherapy would have an advantage over those who just received medication under psychiatrist follow-up and that those who received both interventions would have an advantage over those who just attended psychotherapy sessions. The results of the two pilot studies found that all patients presented scores below the SCS cut-off (24) (Parsons, Bimbi, & Halkitis, 2001) upon completion of the intervention. Brazilian participants scored an average of 32 in SCS (Scanavino et al., 2016). Then, we theorized that patients who would receive the combination of interventions would report a reduction in their SCS scores to 23, that participants of the STPGP-RPGT would result in minor improvements (i.e., SCS score of 25), that participants of the PT would report the least improvements (i.e., SCS score of 27). Therefore, the sample required to analyze variance with three groups, a standard deviation of 5, for a test with 80% statistical power and alpha of 5% present 33 participants per group. We increased the sample size estimation by 35%, resulting in 135 participants, because of our knowledge of low adherence to treatment among those with CSB.

Given the number of participants who dropped out from the study between the baseline and 25th week was 57 (42.2%), and between the baseline and 34th week was 68 (50.4%), we made our analysis in three phases: complete case analysis (Phase 1); adherence vs. non-adherence (Phase 2); adherent to STPGP-RPGT vs. adherent to PT vs. adherent to both interventions vs. non-adherent to interventions vs. control group (Phase 3). The control group is a subsample defined for Phase 3 data analysis, based on those who did not attend any psychotherapy session or did not take any pill or medication. We also estimated the risk of non-adherence by analyzing the frequency of problematic sexual behavior.

In phase 1 analysis, we repeated the estimations excluding participants who received mood stabilizers exclusively (2.3%) and all those who received mood stabilizers (23%) to investigate if there was an association between SCS and specific medication class.

We investigated the effect of treatment adherence, considering PT adherence greater than 80% registered

medication taken and STPGP-RPGT adherence with more than 18 total therapy sessions (quantile 75%) attended. The participant must be adherent in both modalities to be adherent in the PT + STPGP-RPGT group. The cut-off scores are based on the literature on adherence (Granger et al., 2005; Osterberg & Blaschke, 2005).

Corresponding analyses were performed excluding patients who receive mood stabilizers exclusively (2.3%) and all who receive them (23%) to investigate whether adherence to treatment was associated with a specific medication class.

Finally, we investigated the proportion of non-adherence according to the proportion of side effects reported for each type of medication taken to investigate the association between adverse effects and non-adherence.

Ethics

The study procedures were in accordance with the Declaration of Helsinki. Medical ethics committee for Analysis of Research Projects (CAPPESQ) of the Clinical Hospital of Faculty of Medicine of University of São Paulo approved the study in 2010, registered as the number 641/10. All subjects were informed about the study, and all provided informed consent. We registered the study in the ClinicalTrials.gov from National Institute of Health, United States of America.

Table 1. Dropout rate between baseline to 25th week and baseline to 34th week

	Baseline – 25th week				Baseline – 34th week			
	N	%	X^2	*P*	N	%	X^2	*P*
Dropout	57	42.2	2.01	0.36	68	50.4	1.9	0.39
PT	15	35.7			19	45.3		
PT + STPGP-RPGT	18	40			21	46.7		
STPGP-RPGT	24	50			28	58.3		

Note. PT = Pharmacological Treatment (psychiatric follow up with prescribed medication); STPGP = Short-Term Psychodynamic Group Psychotherapy; RPGT = Relapse Prevention Group Therapy

RESULTS

Simple randomized sampling assigned participants to respective arms using a random sequence of numbers generated by statistical software. In total, 42 participants were randomized to PT, 48 to STPGP-RPGT, and 45 to PT + STPGP-RPGT intervention (see Fig. 1).

Regarding attrition between baseline and 25th week, and 34th week measurements, there were no statistical differences (Table 1). We assumed that data were missing at random as there were no significant differences between the participants who completed the SCS at the 25th/34th week and those who did not regard SCS baseline scores, age, years of education, race, marital status, employment situation, sexual orientation, monthly income, and therapeutic modality.

Phase 1.

There were no significant differences between groups on sociodemographic characteristics at baseline (Table 2).

The time effect for Phase 1 analysis has a significantly decreased impact on SCS scores, F (2, 132) = 26.92, P < 0.001, ES = 0.29. and Post hoc comparisons test shows significant improvement from baseline to 25th-week measurement (t = 6.1; P < 0.001; ES = 0.75); and from baseline to 34th-week (t = 6.6; P < 0.001, ES = 0.79); there was no difference of SCS scores between the 25th and 34th week (t = 0.4, P = 0.67, ES = 0.05) (see Fig. 2).

Table 2. Sociodemographic characteristics of participants

		Total sample		PT		PT + STPGP-RPGT		STPGP-RPGT		*P*	ES
		N	%	N	%	N	%	N	%		
Age[1,2]		37.1	9.0	36.2	8.3	37.0	8.8	38.0	9.8	0.69	0.007
Income[1,2]		5526.7	5732.8	5207.1	4457.3	6171.1	7908.2	5202.1	4150.2	0.88	0.006
Sexual Orientation[3]	Gay or Bisexual	62	45.9	18	42.9	22	48.9	22	45.8	0.85	0.049
	Heterosexual	73	54.1	24	57.1	23	51.1	26	54.2		
Marital status[3]	Married/Stable Union	53	39.3	17	40.5	16	35.6	20	41.7	0.82	0.055
	Single/divorced	82	60.7	25	59.5	29	64.4	28	58.3		
Race[3]	White men	98	72.6	27	64.3	36	80.0	35	72.9	0.26	0.141
	Black, Asian, indigenous people	37	27.4	15	35.7	9	20.0	13	27.1		
Educational level[3]	Preschool	3	2.2	2	4.8	0	0.0	1	2.1	0.16	0.185
	Elementary School	21	15.6	11	26.2	6	13.3	4	8.3		
	High School	76	56.3	22	52.4	26	57.8	28	58.3		
	Higher education	35	25.9	7	16.7	13	28.9	15	31.3		

Note. PT = Pharmacological Treatment (psychiatric follow up with prescribed medication); STPGP = Short-Term Psychodynamic Group Psychotherapy; RPGT = Relapse Prevention Group Therapy. Income in Brazilian currency.
Note 1. Mean and standard deviation. Eta effect size.
Note 2. Kruskal–Wallis Test.
Note 3. Cramer's V effect size.

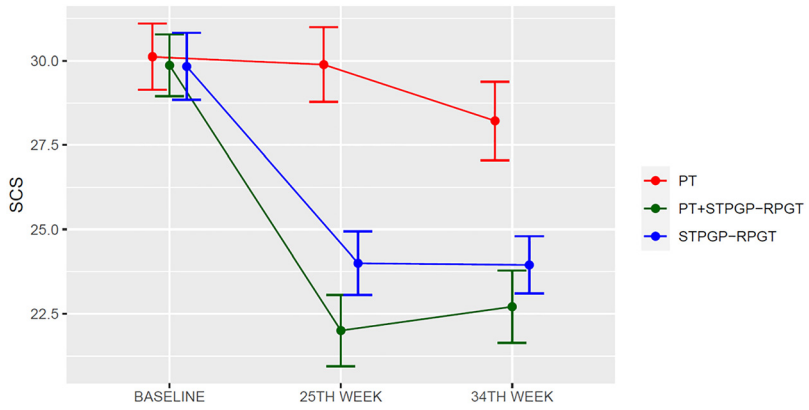

Fig. 2. SCS means in Baseline, 25th week and 34th week for each group treatment (PT, PT + STPGP-RPGT and STPGP-RPGT)
Note 1. SCS = Sexual Compulsivity Scale; PT = Pharmacological Treatment (psychiatric follow up with prescribed medication); STPGP = Short-Term Psychodynamic Group Psychotherapy; RPGT = Relapse Prevention Group Therapy.
Note 2. The bars correspond to Standard Error.

There were significant differences between group treatments in the 25th week measurement. The PT differed from the two group treatments (PT + STPGP-RPGT: $t = 4.17$, $P < 0.001$, ES = 1.14) (STPGP-RPGT: $t = 3.02$; $P = 0.007$, ES = 0.85) with a significant higher value. At 34th-week, the PT group showed higher values than PT + STPGP-RPGT ($t = 2.71$, $P = 0.026$, ES = 0.79) (see Fig. 2).

A significant interaction effect was found between timeline and group treatment, F (4, 128) = 2.62, $P = 0.038$, ES = 0.08), showing that the PT group improved less than PT + STPGP-RPGT and STPGP-RPGT (see Table 3 and Fig. 2). Post hoc analysis indicated that PT group produced a significantly smaller compulsivity change than both STPGP-RPGT ($t = 2.41$, $P = 0.038$; ES = 0.60) and PT + STPGP-RPGT groups ($t = 3.15$, $P = 0.007$, ES = 0.74). We found no evidence that PT + STPGP-RPGT performed significantly better than the STPGP-RPGT ($t = -0.61$, $P = 0.547$; ES = −0.15).

We repeated phase 1 analysis, excluding participants who received mood stabilizers exclusively (2.3%), and kept only time and between-group effects, but we no longer had interaction effects, F (4, 126) = 2.27, $P = 0.066$, ES = 0.067. On the other hand, when excluding the 20 participants (20.3%) who received mood stabilizers, either alone or with SSRIs, we still had the interaction effect,t F (4, 108) = 2.72, $P = 0.033$, ES = 0.092 as the entire sample.

Figure 3 shows the proportion of problematic behaviors across the groups. There is no statistically significant difference for each problematic behavior distribution across the group treatments (pornography: $P = 0.58$; masturbation:

Table 3. Sexual Compulsive Scale scores from baseline to follow-up for between-group effect (Phase 1), adherence to treatment (Phase 2) and intra-group effect (Phase 3)

		Baseline				25th week				34th week				
		N	*P*	M	SD	N	*P*	M	SD	N	*P*	M	SD	P^3
Phase 1: Group	PT	42	0.970[1]	30.1	6.3	27	<0.001***	29.8	7.1	23	0.024*	28.2	7.5	0.038*
	PT + STPGP-RPGT	45		29.8	6.1	27		22.0	7.0	24		22.7	7.2	
	STPGP-RPGT	48		29.8	6.8	24		24.0	6.5	20		23.9	5.8	
Phase 2: Adherence to treatment	No	94	0.469[2]	29.7	6.2	44	0.006**	27.4	7.1	36	0.027*	26.7	6.1	0.062
	Yes	41		30.3	6.9	34		22.6	7.6	31		22.8	7.9	
Phase 3: Group treatment	PT	18	0.069[1]	29.7	7.4	11	–	25.6	10.3	8	–	25.0	10.8	–
	PT + STPGP-RPGT	4		34.2	3.4	4		24.0	6.3	4		28.5	6.7	
	STPGP-RPGT	19		30.1	6.9	19		20.6	5.5	19		20.7	6.2	
	Non adherence	77		29.7	6.1	43		27.3	7.1	35		26.5	6.1	
	Control	17		29.6	6.9	1		31.0		1		34.0		

Note. PT = Pharmacological Treatment (psychiatric follow up with prescribed medication); STPGP = Short-Term Psychodynamic Group Psychotherapy; RPGT = Relapse Prevention Group Therapy.
Note 1. Nonparametric Kruskal Wallis test.
Note 2. Nonparametric Mann Whitney U test.
Note 3. ANOVA two ways repeated measure Time-group interaction effect.
Note. $^{*}P < 0.05$; $^{**}P < 0.01$ and $^{***}P < 0.001$.

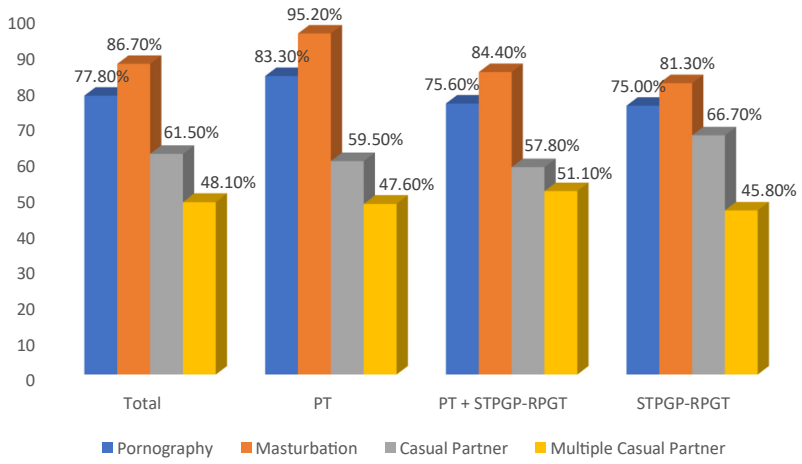

Fig. 3. Presence of problematic behaviors across treatment groups
Note: PT = Pharmacological Treatment (psychiatric follow up with prescribed medication); STPGP = Short-Term Psychodynamic Group Psychotherapy; RPGT = Relapse Prevention Group Therapy.

$P = 0.13$; casual partner: $P = 0.65$; multiple casual partners: $P = 0.88$).

Phase 2.

Considering treatment adherence phase 2 analysis, 41 (30.4%) participants were adherent, and 94 (69.6%) were not adherent. Moreover, the measurement analysis shows a significant difference between adherent and non-adherent groups in the 25th week and 34th week (see Table 3).

There was no significant interaction effect between timeline and treatment adherence, despite adherent patients showing more average decreasing scores than non-adherent patients (see Table 3).

No modification of treatment adherence on sexual compulsivity scores was found when excluding patients who received exclusively mood stabilizers (2.3%, $P = 0.017$) and all who received them (23%, $P = 0.047$).

The side effects were present in 44 (62%) of all participants assigned to treatment modalities involving prescribing medication, by 33 (75%) of those who received SSRI and 11 (25%) of those who received SSRI and mood stabilizers. Those who received just mood stabilizers did not report side effects.

The side effects presented by participants were diminishing sexual desire (32.4%), daily sleepiness (22.5%), delayed ejaculation (17.9%), difficulties getting an erection (8.5%), anxiety (8.5%), difficulties in reaching orgasm (2.8%), alterations on cognition (2.8%), depression (1.4%), nocturn sleep alterations (1.4%), dizziness (1.4%), headache (1.4%), and glaucoma (1.4%), gain of weight (1.4%), diarrhea (1.4%), dyspepsia (1.4%). The distribution of side effects was not associated with any type of medication ($P > 0.05$).

Regarding the association between side effects and non-adherence to treatment, we did not find evidence of association with non-adherence when considering the participants who received medication ($X^2 = 0.15$; $P = 0.697$), neither for those who received SSRI; ($X^2 = 1.94$; $P = 0.163$),

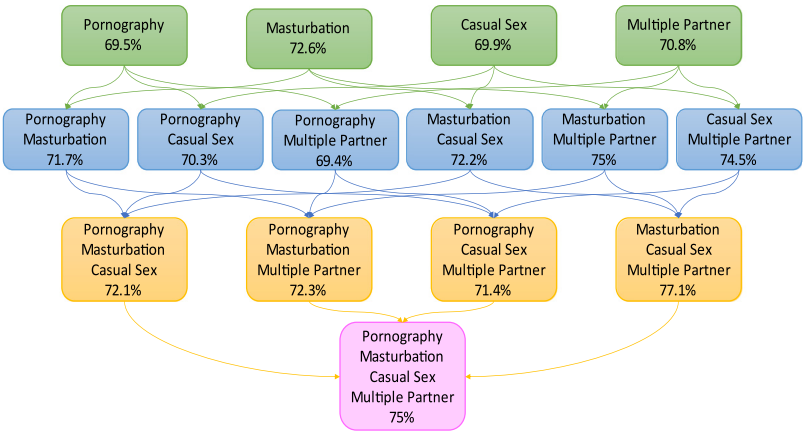

Fig. 4. Nonadherence risk based on one (green block), two (blue block), three (orange block) or the four (pink block) problematic behaviors
Note: The risk of non-adherence to treatment ranged from 69.4% to 77.1%, depending on the problematic behaviors reported, but compulsive masturbation behavior is related to a greater non-adherence risk proportion (72.6%), while compulsive pornography is related to a lower risk proportion (69.4%). Moreover, when compulsive masturbation behavior is reported to be associated with compulsive casual sex and multiple sexual partners, greater proportions of non-adherence to treatment occur (77.1%).

and those who received SSRI and mood stabilizers (X^2 = 0.88; P = 0.349).

Figure 4 presents the treatment risk of non-adherence according to one or several problematic sexual behaviors.

Phase 3.

In phase 3, those with treatment adherence were separated into three treatment modalities, namely, PT (n = 18), PT + STPGP-RPGT (n = 4), and STPGP-RPGT (n = 19). Those with non-adherence to treatment were separated into the non-adherence (n = 77) and control (those who did not begin any at all treatment, n = 17) groups.

The high number of drop-outs made it impossible to analyze any post-treatment evaluation in Phase 3. Table 3 shows the number of participants and SCS measurements evaluation in baseline, 25th week, and 34th week in Phase 3.

DISCUSSION

Although most treatment studies report improvements in CSB (Hook et al., 2014), to the best of our knowledge, the present RCT is the first with CSB patients showing between-group treatment effects on a CSB standardized measure when comparing intervention to active control. Indeed, in an RCT comparing acceptance and commitment therapy, participants reported improvements in CSB post-treatment compared to pretreatment. However, the comparison group was on a waiting list (Crosby, 2011). Furthermore, a double-blind RCT comparing citalopram with placebo did not find a treatment effect of the experimental intervention on the CSB measure (Wainberg et al., 2006). The authors suggested that combining different types of interventions may result in an increased treatment effect than medication. Our results provide support for this supposition.

Although our patients received medication with effects on mood (Ravindran & Stein, 2010), impulse (Stanford, Anderson, Lake, & Baldridge, 2009), and sexual regulation (Marazziti & Dell'Osso, 2006), medication alone was associated with the least improvement and small effect size, while the psychodynamic therapy resulted in large effect size. These results align with previous meta-analyses, which suggest that psychodynamic therapy may achieve a larger effect size than medications (Leichsenring & Leibing, 2003; Shedler, 2010). A possible explanation for our results may be because, beyond being efficacious in treating CSB manifestations, such as emotional dysregulation, impulsivity (Munroe-Blum & Marziali, 1995), and compulsivity (Crits-Christoph et al., 2001), psychodynamic therapy increases the understanding of the effects of early stress experiences on interpersonal and sexual relationships in adulthood (Blagys & Hilsenroth, 2006). This results in an enhanced awareness of negative emotional states, connections among emotional states and compulsive symptoms (Burum & Goldfried, 2007), and emotion regulation skills, particularly stress-related emotions (Shedler, 2010). Therefore, beyond regulating CSB symptoms, psychodynamic therapy likely results in patients developing skills to manage CSB symptoms on their own. Although we could not run statistical analysis in Phase 3, the descriptive data suggest that the difference between PT and the other modalities in Phase 1 also appears when considering just those participants who were adherent. The PT adherent participants diminished on average by five points, while the STPGP-RPGT and PT + STPGP-RPGT adherent participants diminished on average by 10 points in sexual compulsivity scores from baseline to 25th week.

Our data show non-adherent patients (n = 94; 69.6%), and some factors may influence this result, such as the high proportion of problematic behaviors, as shown in Fig. 4. We did not run any statistical tests because of the low observations of combined problematic behaviors. However, the interest in reporting descriptive statistics is still relevant, given there are several studies investigating the relationship between problematic behaviors to negative outcomes (Böthe et al., 2019, 2021; Cooper, Delmonico, Griffin-Shelley, & Mathy, 2004; Scanavino, Ventuneac et al., 2013; Zawacki et al., 2005). In general, presenting one or combined problematic behaviors are related to a high risk of non-adherence, with small differences according to the type of problematic behaviors. CSB patients show difficulties maintaining perseverative errors and lack of learning when sexually stimulated (Messina, Fuentes, Tavares, Abdo, & Scanavino, 2017). Patients with more sensation-seeking have low compliance with treatment (Bakhshipour-Rudsari & Karimpour-Vazifehkhorani, 2021). The severity of sexual compulsivity and the potential highly associated sensation seeking (Gullette & Lyons, 2005; Kalichman & Rompa, 1995; Scanavino et al., 2016) likely influence the non-adherence to treatment since those patients present low compliance to treatment (Bakhshipour-Rudsari & Karimpour-Vazifehkhorani, 2021). Likely highly sexually compulsive patients are more prone to engage in those behaviors and maintain an impulsivity pattern which impairs adherence to treatment. We cannot compare it among the problematic behaviors because we did not make statistical tests. However, compulsive masturbation is associated with a greater risk of non-adherence as a single (72.6%), and associated with casual sex and multiple partners (77.1%) behavior. These findings may be related to the fact that there are several factors associated with the activation of compulsive masturbation. A twin study on problematic masturbatory behavior in children observed that genetic factors substantially influenced the masturbatory behavior resulting in a greater proportion of it among monozygotic twin pairs compared to dizygotic pairs (Långström, Grann, & Lichtenstein, 2002). Beyond genetic, emotional dysregulation, particularly anxiety, seems to activate masturbatory behavior in CSB individuals as a way to release (Bancroft, 2008; Miner, Dickenson, & Coleman, 2019). Finally, after the appearance of the internet, for those with CSB, occurred the opportunity for a blending of masturbatory behavior with other behaviors, such as online pornography consumption, but also in interactive patterns via chat rooms and other online networking (Bancroft, 2008), sometimes resulting in engaging in presential encounters for casual sex. The multiple ways to activate compulsive masturbation make that masturbation a problematic behavior more present in individuals with greater severity of CSB, like in the present

study (Fig. 3). Future studies with proper methodology can investigate the role of problematic behaviors from a deeper perspective.

Moreover, when compulsive masturbation is reported to be associated with multiple sexual partners and compulsive casual sex, which are the behaviors more related to sexual risk behaviors (Böthe et al., 2019; Scanavino, Ventuneac et al., 2013), the greater proportions of non-adherence to treatment occur, according to Fig. 4. Therefore, we can think of an association of multiple risks, considering that those who do not adhere to treatment will likely expose themselves more to risky behaviors.

Swift, Greenberg, Tompkins, and Parkin (2017) report that among varied conditions, like binge-eating disorders, borderline personality disorder, and post-traumatic stress disorder, participants have more chance of treatment discontinuation when it is only pharmacotherapy since patients report more preference for psychotherapy. It supports our Phase 3 data on adherent participants, in which 10 (from 18) participants from the pharmacological group dropped out from the baseline to 34th week, while the psychotherapy groups maintained the same number of participants from baseline until the 34th week.

Regarding limitations, in Phase 3, we could not make statistical analysis in 25th and 34th weeks because of the limited number of observations in some categories. Particularly the adherent group to medication and psychotherapy presented the smaller number of participants (just four), likely because they have to reach two adherence criteria, namely, taking 80% of the medication prescribed and simultaneously attending to at least 75% of the psychotherapy sessions, while the other groups should meet just one adherence criteria. However, the descriptive data is consistent with Phases 1 and 2. More importantly, our data showed an elevated drop-out rate; in this situation, the more proper conduction is to analyze complete cases and discuss the limitations of the data (Jakobsen, Gluud, Wetterslev, & Winkel, 2017). We followed such a recommendation, investigating the impact of non-adherence on therapeutic effect. We also did not use a run-in phase for diminishing the drop-out. However, it increased the study's external validity by revealing the target population's exact behavior, which is one strength of this study.

We got a high (n = 68; 50.4%) drop-out rate. However, we did not find differences regarding baseline sociodemographics, clinical characteristics, and treatment modalities among those who dropped out and those who did not drop out of the study, indicating there was no attrition bias. A high drop-out rate is typical of participants with impulsivity and compulsivity symptomatology, such as gambling disorders outpatients (50.3%) (Bickl et al., 2021), problematic pornography use (89.4%) (Böthe et al., 2021) and a previous CSB study, 23 participants of the therapeutic arm did not complete the last time of the study (33%) (Hallberg et al., 2019). Longer treatment protocols (36 weeks) (Bickl et al., 2021), as our study, may result in greater drop-out rates than lower (seven weeks) (Hallberg et al., 2019). Also, intervention without therapists' prominent action, which depends on more autonomous behavior (Böthe et al., 2021), may result in a greater drop-out rate. Moreover, studies have addressed clinical factors for understanding drop-out of treatments for conditions involving impulsivity and compulsivity symptomatology (Brorson, Ajo Arnevik, Rand-Hendriksen, & Duckert, 2013). Regarding clinical reasons, the most consistent finding is the maladaptive personality functioning, which may increase problems with the therapeutic team (Ball, Carroll, Canning-Ball, & Rounsaville, 2006; Brorson et al., 2013; Swift et al., 2017) or activation of avoidance coping mechanisms (Chen, Jiang, Luo, Kraus, & Bőthe, 2022; Lewczuk et al., 2020) resulting in dropping out the study. It is a relevant point that may be applied to our study since CSB seeking treatment sample presents a high rate of problems with personality, particularly high sensation seeking, which is correlated with impulsivity, and low self-directedness, which impair self-care (Amaral, Abdo, Tavares, & Scanavino, 2015). Both personality alterations may increase the chances of dropping out of the treatment. Regarding treatment reasons, the most consistent is low treatment alliance (Brorson et al., 2013). We did not measure it in our study. Our phase 3 analysis showed a greater proportion of retention of participants who adhered to treatment in the psychotherapy modality group when we suppose there is a high treatment alliance (Lowenkron, 2008; Shedler, 2010). However, we did not find differences among treatment modalities in Phase 1, so we cannot make any conclusion in this way. Further studies can investigate this point.

The fact of not using a single medication may limit the inferences on the results of the pharmacological treatment in our study. However, we conducted an analysis excluding those who just took mood stabilizers and those who took mood stabilizers with or without SSRI, regarding the outcomes of sexual compulsivity, adherence to treatment, and side effects, and most of the results did not show differences between those medications. However, those analyses were just from our study, and more investigations should be done to confirm those findings. Curiously, the only result that did not confirm Phase 1 findings when doing those analyses per class of medication was the loss of interaction effect among time and treatment when we took out those participants who had just mood stabilizers prescribed (n = 2; 2.3%). We can think of taking out participants using just mood stabilizers; part of the difference between PT and other treatment modalities diminished. Therefore, participants taking just the mood stabilizers would not get better on CSB symptoms than those receiving SSRI. However, only two participants were taking just mood stabilizers, which points out more to statistical issues than a clinical reason for this occurrence. Statistical issues can result when splitting the PT group into three small subgroups; we cannot achieve the minimum statistical power to run this analysis. The literature has been studying the effect of mood stabilizers on impulse control disorders with some positive results (Grant, Kim, & Odlaug, 2007; Yip & Potenza, 2014). Particularly mood stabilizers with glutamatergic mechanisms (e.g., topiramate) seem to mediate different aspects of addictive behaviors such as

compulsive use or behavior, craving, and seeking behavior (Olive, Cleva, Kalivas, & Malcolm, 2012). More studies are needed to clarify controversial data.

Despite being unable to make statistical estimations, Phase 3 descriptive data allow some interesting observations for future studies. First, considering the adherent groups, the average scores of SCS decreased more in the psychotherapy groups than in the pharmacological group. Second, adherence to psychotherapy may also affect participants' retention because none of the adherent participants in the psychotherapy groups dropped out, while many participants dropped out in the adherent pharmacological group. Third, the non-adherent groups presented a high drop-out rate and no diminishing average scores of SCS. Further psychotherapy studies may explore the aspects of treatment effect and retention rate. One aspect to be further investigated is motivation since group psychotherapy seems to increase cohesion and motivation (Burlingame et al., 2003; Cuijpers et al., 2019; lo Coco, Gullo, Prestano, & Burlingame, 2015).

Regarding adherence to medication, we used two different measures. For those who choose to pick the medications up in the hospital pharmacy, the adherence to taking the medication was measured through the hospital pharmacy electronic system, which estimates the adherence rate based on the refill of the medication registered. Those participants who chose to buy the medication in private pharmacies had the adherence estimated retrospectively through medical records on the intake of medications based on the Coldham et al. (2002) method. Unfortunately, we do not have plasma levels measurement of the substances prescribed for this study, which would increase the estimations' accuracy. However, the hospital pharmacy electronic system, which estimates the adherence rate based on the medication refill, is well recognized by the literature (McMahon et al., 2011), and the Coldham et al. (2002) method is rigorous for considering adherent participants.

Surprisingly 95% of the participants who decided to buy the medication at a private pharmacy did not adhere. Therefore, it seems they present a different behavior than those who get the medication at the hospital pharmacy. To get the medication at the hospital pharmacy, participants have to engage in hospital procedures, such as waiting in lines in the pharmacy until they are attended to and coming back to the hospital monthly to get a medication refill, suggesting they are committed to the therapeutic protocol. Brorson et al. (2013) and Grover, Mallnaik, Chakrabarti, and Mehra (2021) found poor therapeutic alliance with the therapeutic team is related to drop-out rate and present negative attitudes. We did not measure therapeutic alliance, but we can infer that those who did not get the medication at the hospital presented a lower therapeutic alliance. Further studies may investigate this inference.

The patient's belief in the treatment and the expectation regarding it is important due to the biological, emotional, and cognitive effects they cause, favoring an initial improvement (Kaptchuk, 2002). The non-blinding of RCT may incur discrepancies in this phenomenon when participants perceive they are not part of an active intervention. As in psychotherapy studies, the double-blind design is considered almost impractical (Enck & Zipfel, 2019). We must consider the possibility of this phenomenon occurring in the present study as a limitation. However, all our interventions were active, reducing the chance of this occurrence.

Our outpatient unit receives people of all gender identities, but most of them are men. Usually, for every 9 or 10 outpatients who search the outpatient unit, 1 woman also searches, which follows the literature (Scanavino, Ventuneac et al., 2013). Because of the low rate of women searching for treatment, we enrolled only men in this first RCT to preserve the statistical inference. However, we recognize the relevance of studying women who search for CSB treatment and that the lack of women and gender-diverse individuals constitutes a limitation of this study.

The several methodological limitations, such as high drop-out and non-adherence rate, not using a single medication in the PT, and not blinding the groups compromise our ability to conclude the efficacy of the PT + STPGP-RPGT and STPGP-RPGT groups over the PT group showed in Phase 1. Therefore it works as a hypothesis to be tested in further studies. However, it can be representative of clinical settings providing insights into the usefulness of different treatment modalities.

A strength of this study is addressing the critical issue of adherence to treatment in CSB. Our data points out the need for new strategies to increase the retention of the participants, which will be critical to treatment evidence. Literature has suggested strategies to overcome drop-out and non-adherence to CSB treatment, such as general (e.g., education on disorder and treatment) (Swift, Greenberg, Whipple, & Kominiak, 2012), specific symptom (e.g., emotion regulation skills strategies) (Lew-Starowicz et al., 2020), and program (e.g., addressing comorbidities in the treatment programs) (Briken, 2020) approaches. Our treatment program involves most of those strategies, but some adaptations may likely be proposed for future studies. First, the psychoeducation approach to the challenges of the CSB treatment may start at the very beginning of the participant's contact with the care unit. Starting a psychoeducational approach just when the formal treatment begins seems to be late. Second, different types of therapeutic stimulus may be considered in the level of symptom approach. For example, participants reporting watching pornography may benefit more from intervention using visual stimuli. Third, the program approach may account for plural therapeutic modalities, considering the diverse symptomatology related to CSB and comorbidities. For example, patients presenting alexithymia may benefit from non-verbal therapy.

Conclusion

The participants who adhered to treatment improved better than those who did not adhere. Moreover, the participants who received psychodynamic therapy improved better than those who just received medication. Although, the high drop-out and non-adherence rates limit the conclusions on

efficacy. Those findings show that it is critical to enhance adherence to CSB treatment. The high percentage of problematic behaviors and impulsivity symptoms seems to impair treatment adherence. More studies are needed to investigate the effectiveness and strategies to improve adherence in CSB.

Funding sources: No financial support was received for this study.

Authors' contribution: MTS: study design, statistical analysis, study analysis, and interpretation of data. AGG: statistical analysis and interpretation of data. JMM: study analysis and interpretation of data. MLSAA: data collection and study analysis. BM: data collection and study analysis. SCR: data collection and study analysis. VBB: data collection and study analysis. CHNA: data collection and study supervision. HT: data collection and study supervision. JTP: study design and study supervision.

Conflict of interest: The authors declare that this work does not have conflicts of interest to report.

SUPPLEMENTARY MATERIALS

Supplementary data to this article can be found online at https://doi.org/10.1556/2006.2023.00004.

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