

# The Interplay Between Problematic Online Pornography Use, Psychological Stress, Emotion Dysregulation and Insomnia Symptoms During the COVID-19 Pandemic: A Mediation Analysis

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**Purpose:** Although a link between problematic online pornographic use (POPU) and insomnia symptoms has been established, psychological and psychopathological mechanisms underlying this relationship are still not clear. Psychological stress and emotion dysregulation have been pointed out as relevant in the development and maintenance of insomnia. This study aims to explore the associations between POPU, psychological stress, emotion dysregulation and insomnia symptoms and to understand the mediating role of psychological stress and emotion dysregulation in the relationship between POPU and insomnia symptoms.

**Participants and Methods:** A sample of 776 Italian adults aged 19–48 years (51.4% female;  $M$  age = 28.49;  $SD$  = 7.33) completed questionnaires regarding demographics, COVID-19-related variables, POPU, psychological stress, emotion dysregulation, and insomnia symptoms.

**Results:** After controlling for demographic covariates and COVID-19-related variables, multiple mediation model showed that higher psychological stress and emotion dysregulation fully mediated the link between POPU and insomnia.

**Conclusion:** The findings underscore the significance of the negative consequences of POPU and underline the importance of working on this and its effects on psychological stress and emotion dysregulation to limit insomnia.

**Keywords:** addictive behaviors, online pornography, problematic online pornographic use, stress, emotion dysregulation, clinical psychology, insomnia

## Introduction

Insomnia is a condition characterized by difficulty in initiating or maintaining sleep associated with psychiatric and physical comorbidities which constitutes a significant public health problem.<sup>1</sup> It impairs an individual daily life and social functioning by increasing fatigue, daytime sleepiness and cognitive impairments.<sup>2</sup> While insomnia disorder has an estimated prevalence of 5–15%,<sup>3</sup> insomnia symptoms have been observed to occur with estimates ranging 30–50% among the adult population.<sup>4</sup>

Given that insomnia is a heterogeneous clinical condition, several models have been developed to explain its multifaceted pathophysiology. According to the well-established Neurocognitive Model, insomnia is highly dependent on individuals' sleep system response to external stressors and dysfunctional coping strategies.<sup>5–7</sup> More specifically,

individual proneness represents a predisposing factor that, with the occurrence of stressful life events, could precipitate acute insomnia episodes which may, in turn, develop into chronic insomnia through maladaptive behavioral coping strategies as a result of conditioned arousal.<sup>7</sup>

In this regard, with the diffusion of the Internet and digital technologies, online activities become additional ways to cope with stressful situations.<sup>8</sup> Although involvement in such activities typically does not imply negative consequences, for a minority of individuals it can lead to reduced social interactions and impaired daily activities.<sup>9</sup> Notably, recent research provided evidence for the association between different forms of problematic Internet use,<sup>10</sup> and the onset and maintaining of sleep disorders. In fact, excessive exposure to artificial blue-spectrum light, usually for internet browsing, can lead to melatonin suppression.<sup>11</sup> Furthermore, users' inability to stop Internet usage (eg, for playing video games or accessing pornography) can negatively affect their sleep-wake schedule.<sup>8</sup> In this regard, problematic online pornographic use (POPU) can be considered a specific type of problematic Internet use<sup>12,13</sup> that includes any use of online pornography leading to significant negative interpersonal or personal consequences for the user.<sup>14</sup> In fact, POPU has been associated with higher relational problems<sup>15,16</sup> and lower mental health.<sup>17</sup> Notably, pornography, for its characteristics, may play a specific role in worsening users' sleep quality<sup>18</sup> because it includes "any material designed to cause or enhance sexual arousal or sexual excitement in the viewer",<sup>19</sup> and excessive pornography use is associated with increased stress and anxiety,<sup>20</sup> social impairment and isolation,<sup>21</sup> sexual dysfunctions<sup>22</sup> and sleep disturbances.<sup>11</sup> Indeed, Cacioppo et al<sup>16</sup> found that POPU was linked to psychological distress and emotional difficulties, which, in turn, were found to be associated with sleep disturbance.<sup>23–25</sup> In the same line, effective emotion regulation abilities were found to be associated with sexual satisfaction and lower levels of POPU by Pepping et al.<sup>26</sup>

Dysfunctional ways of dealing with stressful situations have been seen to affect the sleep-wake schedule. Alterations in cognitive arousal systems are traditionally considered a risk factor of insomnia symptoms<sup>5</sup> and the ability of an individual to regulate emotion plays a role in decreasing the detrimental effects of emotional stress on sleep physiology.<sup>27</sup> Balleisio et al<sup>28</sup> observed that higher pre-sleep intrusive thoughts affected sleep continuity. Similarly, Li et al<sup>29</sup> and Du et al<sup>30</sup> showed that pre-sleep rumination, as a dysfunctional emotion regulation strategy, could exacerbate anxiety resulting in disrupted sleep, and that resilience, as an effective self-adjustment to stressful situations, would moderate stress influence on sleep. A dysregulated stress response has been shown to disrupt prefrontal control involved in emotion regulation, thus leading to one's inability to properly adapt to situational demands<sup>31</sup> which lead, in turn, to worsening of symptoms such as sleep disturbances. Moreover, maladaptive self-regulation strategies, such as problematic internet use and POPU, are associated with an increase in psychological stress.<sup>32</sup>

In sum, the available literature reports consistent associations between POPU, psychological stress, difficulties in regulating emotions and insomnia symptoms.<sup>27,33</sup> However, to date, no study has investigated the associations between these variables in a single model, thus limiting our ability to comprehend how these related factors operate as a whole. Therefore, this study aims to further understand the link between POPU and insomnia symptoms taking into account the mediation role played in this relationship by psychological stress and emotion dysregulation. In addition, given the negative impact of COVID-19 pandemic on insomnia symptoms,<sup>34,35</sup> we also controlled for COVID-19 related variables.

The current study has two aims: (1) to explore the multiple mediating role of emotion dysregulation and psychological stress between POPU and insomnia symptoms; (2) to examine the sequential relationship between stress and emotion dysregulation. Specifically, we hypothesized that:

H1. High POPU would be associated with increased insomnia symptoms;

H2. Psychological stress would mediate the association between POPU and insomnia symptoms;

H3. Emotion dysregulation would mediate the association between POPU and insomnia symptoms;

H4. Psychological stress and emotion dysregulation would sequentially mediate the association between POPU and insomnia symptoms.

## Materials and Methods

### Procedure

Data were collected from general population following a snowball sampling method.

Inclusion criteria were a) age of 18 years or older, b) Italian native language, and c) living in Italy during the second wave of COVID-19. Participants were requested to fill out a 20-min anonymous web survey on the Microsoft Azure platform during the second wave of the COVID-19 pandemic in Italy (18 December 2020–18 January 2021). The web-survey was promoted via university platforms and on different social media and virtual learning environments. Furthermore, respondents were asked to spread the survey among acquaintances. Participants signed the informed electronic consent form before accessing the survey. The study was approved by the local ethics committee (CERIP – Comitato Etico del Centro di Ricerca e di Intervento Psicologico – University of Messina, prot. n. 17758). All procedures were conducted in accordance with the Declaration of Helsinki and its later advancements.

### Measures

#### Socio-Demographic Information

In this section information about gender, age, nationality, ethnicity, education, family (ie, single, married or in a stable relationship, divorced or separated, and widow) and occupational statuses (ie, student, working student, employed, freelance, unemployed, and retired) was collected.

#### COVID-19-Related Variables

Three ad hoc items (yes/no) were used to assess the participant direct or indirect experience related to COVID-19 (ie, personal or someone close infection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and quarantine history in the last 3 months).

#### Problematic Online Pornography Use

The Cyber Pornography Addiction Test (CYPAT)<sup>16</sup> was used for assessing the risk of POPU. It is a self-report scale consisting of 11 items (eg, “I told myself to stop using online pornography but I didn’t succeed”) scored on a 5-point Likert scale (1 = never, 5 = always). The total score ranged from 11 to 55, with higher scores indicating greater POPU. No cut-off score has been developed for this scale. Following Jacobs et al,<sup>36</sup> we used a total CYPAT score range of 23 to 55, to identify users with high levels of POPU. Previous studies showed good psychometric properties and validity of this instrument.<sup>16,37</sup> In the present study, Cronbach’s  $\alpha$  was 0.93.

#### Emotion Dysregulation

The Italian version of the Difficulties in Emotion Regulation Scale (DERS;<sup>38</sup> original version by Gratz and Roemer)<sup>39</sup> was used to assess participants’ emotion dysregulation. It is a self-report scale containing 36 items (eg, “When I’m upset, I acknowledge my emotions”). Participants were asked to rate their responses on a 5-point Likert scale, ranging from 1 (Almost never) to 5 (Almost always). Higher total scores indicate greater emotion dysregulation. The DERS is a widely used tool that demonstrates good psychometric properties in different settings and cultures.<sup>40,41</sup> In the present study, Cronbach’s  $\alpha$  was 0.93.

#### Psychological Stress

The Stress subscale of the Italian version of the Depression Anxiety Stress Scales-21 (DASS-21-S;<sup>42</sup> original version by Lovibond and Lovibond 1995)<sup>43</sup> was adopted to evaluate participants psychological stress. The DASS-21-S subscale includes 7 items (eg, “I felt that I was using a lot of nervous energy”) rated on a 4-points Likert scale ranging from 0 (Did not apply to me at all) to 3 (Applied to me very much, or most of the time). Subscale scores range from 0 to 21, where higher scores indicate greater psychological stress. The DASS-21 is an internationally recognized screening tool for psychological stress that showed good psychometric properties.<sup>44</sup> In the present study, Cronbach’s  $\alpha$  was 0.90.

#### Insomnia Symptoms

The Insomnia Severity Index (ISI)<sup>45</sup> was used to assess participants’ insomnia symptoms that occurred within the

previous 2 weeks. It is a self-report instrument that includes seven items (eg, “How worried/distressed are you about your current sleep problem?”) rated on a 5-point Likert scale from 0 (Not at all) to 4 (Very much). The total score ranges from 0 to 28, where higher scores indicate higher levels of insomnia symptoms. The ISI has been shown to be a reliable and valid screening tool for insomnia symptoms.<sup>46</sup> In the present study, Cronbach’s  $\alpha$  was 0.85.

## Data Analytic Strategy

All statistical analyses were performed using SPSS 21.0 for Mac. Descriptive statistics were computed for all study variables. Univariate normality was examined through skewness and kurtosis.

Correlations between variables were computed using point-biserial correlations between dichotomous and continuous variables and Pearson’s correlation for continuous variables.

The hypothetical mediating role of psychological stress and emotion dysregulation in the relationship between POPU and insomnia was tested using Hayes’ SPSS macro PROCESS.<sup>47</sup> Specifically, Model 6 was performed to assess the significance of all the hypothesized relation between the study variables, controlling for both demographic covariates (ie, age and gender) and COVID-19 related variables (ie, someone close infected with SARS-CoV-2, having been in quarantine, being infected-with SARS-CoV-2). The 95% bias-corrected confidence interval (CI) was examined on 5000 bootstrap samples. Bootstrapping is a random resampling method that “makes no assumption about the shape of the distributions of the variables or the sampling distribution of the statistic” (p. 722).<sup>48</sup> The indirect effect of POPU on insomnia through psychological stress and emotion dysregulation is considered statistically significant if CI does not contain zero.<sup>47</sup> All the results with an  $\alpha$  value lower than 0.05 were considered significant.

## Results

### Sample Socio-Demographics

Analyses were performed on a total of 776 participants, aged 19–48 years ( $M = 28.49$ ,  $SD = 7.33$ ), that voluntarily took part in our survey. Of the total participants, 399 (51.42%) were male, and 756 (97.42%) of Italian origin. As for their ethnicity, 765 (98.58%) were European, 10 (1.29%) were African, and 1 Latino-American (0.13%). Most of the participants completed secondary higher education ( $n = 501$ , 64.56%) and were single ( $n = 432$ , 55.67%). With regard to occupational status, 309 (39.82%) participants were employees. There was no significant association between participants’ gender and age ( $t_{(774)} = -1.21$ ,  $p = 0.23$ ).

### Preliminary Analysis

Descriptive statistics for the scales used in this study are reported in Table 1. As expected for a nonclinical sample, the mean score of the CYPAT was in the nonclinical range. Specifically, 45 participants (11.3%) showed a high level of POPU. In addition, 385 (49.61%) participants reported to have had a close one infected with SARS-CoV-2, 149 (19.20%), had a quarantine history and 57 (7.35%) had been infected with SARS-CoV-2 in the past 3 months.

As shown in Table 2, correlation analysis revealed a pattern of significant and positive associations between all main investigated variables. In addition, being male was significantly and positively associated with higher levels of POPU, as well as significantly and negatively related with insomnia symptoms and stress. Younger age was significantly and

**Table 1** Descriptive Statistics for the Used Scales (N = 776)

	Ranges	Overall Mean	Std. Deviation	Skewness	Kurtosis
CYPAT	1–53	13.61	5.88	2.81	9.01
DASS-21-S	0–21	8.83	5.06	0.31	–0.44
DERS	40–160	83.91	21.80	0.52	–0.40
ISI	0–27	5.54	4.60	1.10	1.27

**Abbreviations:** ISI, Insomnia Severity Index; CYPAT, Cyber Pornography Addiction Test; DERS, Difficulties in Emotion Regulation Scale; DASS-21-S, Depression Anxiety Stress Scales-21-Stress.

**Table 2** Intercorrelations Between Variables of Interest

	1	2	3	4	5	6	7	8	9
1. Age	1	0.04	0.00	<b>0.08*</b>	0.02	-0.04	-0.03	<b>-0.21**</b>	<b>-0.22**</b>
2. Gender		1	-0.03	<b>-0.09*</b>	<b>-0.07*</b>	<b>-0.08*</b>	<b>0.20**</b>	-0.03	<b>-0.08*</b>
3. COVID1			1	<b>0.29**</b>	<b>0.16**</b>	-0.06	0.07	-0.02	-0.05
4. COVID2				1	<b>0.44**</b>	-0.02	-0.05	-0.04	-0.01
5. COVID3					1	-0.02	-0.03	-0.04	-0.13
6. ISI						1	<b>0.10**</b>	<b>0.34**</b>	<b>0.46**</b>
7. CYPAT							1	<b>0.30**</b>	<b>0.14**</b>
8. DERS								1	<b>0.54**</b>
9. DASS-21-S									1

**Notes:** Bold values indicate significant p-values. \*Correlation is significant at the 0.05 level (2-tailed). \*\*Correlation is significant at the 0.01 level (2-tailed).

**Abbreviations:** COVID1, someone close infected with SARS-CoV-2; COVID2, having been in quarantine; COVID3, being infected with SARS-CoV-2; ISI, Insomnia Severity Index; CYPAT, Cyber Pornography Addiction Test; DERS, Difficulties in Emotion Regulation Scale; DASS-21-S, Depression Anxiety Stress Scales-21-Stress.

positively associated with higher psychological stress and emotion dysregulation. No significant associations were found between COVID-19-related variables and main investigated variables.

## The Mediation Model

In order to test the mediating effect of stress and emotion dysregulation on the relationship between POPU use and insomnia, a multiple mediational analysis has been conducted. Results supported the hypothesized model. Controlling for age ( $B = 0.05$ ,  $t = 2.35$ ,  $p = 0.019$ ), gender (females coded as 1, males coded as 2;  $B = -0.46$ ,  $t = -1.52$ ,  $p = 0.13$ ), and COVID-19 related variables (someone close infected with SARS-CoV-2 coded as 1, someone close not infected with SARS-CoV-2 coded as 2,  $B = -0.34$ ,  $t = -1.11$ ,  $p = 0.27$ ; having been in quarantine coded as 1, having not been in quarantine coded as 2,  $B = -0.11$ ,  $t = -0.25$ ,  $p = 0.80$ ; being infected with SARS-CoV-2 coded as 1, having not been infected with SARS-CoV-2 coded as 2,  $B = -0.12$ ,  $t = -0.21$ ,  $p = 0.83$ ), POPU positively predicted psychological stress ( $B = 0.14$ ,  $t = 4.63$ ,  $p < 0.001$ ) and emotion dysregulation ( $B = 0.87$ ,  $t = 4.81$ ,  $p < 0.001$ ). Psychological stress positively predicted emotion dysregulation ( $B = 2.06$ ,  $t = 15.78$ ,  $p < 0.001$ ). Both psychological stress and emotion dysregulation positively predicted insomnia ( $B = 0.36$ ,  $t = 10.36$ ,  $p < 0.001$  and  $B = 0.03$ ,  $t = 3.62$ ,  $p < 0.001$ , respectively). Direct effect ( $B = 0.01$ ,  $t = 0.53$ ,  $p = 0.60$ ), and total effect ( $B = 0.10$ ,  $t = 3.50$ ,  $p < 0.001$ ) of POPU on insomnia were not significant and significant, respectively.

Analysis of the bias-corrected confidence intervals of the indirect effects in the bootstrapped samples further revealed that all indirect effects of the model were significant, further corroborating the sequential mediation of psychological stress and emotion dysregulation (with scores of psychological stress predicting emotion dysregulation) in the relationship between POPU and insomnia. Thus, higher psychological stress and emotion dysregulation fully mediated the link between POPU and insomnia. The total model was significant,  $F(8767) = 29.45$ ,  $p < 0.001$  and accounted for a significant amount of variance in adolescent problematic SNSs use ( $R^2 = 0.235$ ), thus supporting the hypothesized path in the relationships between the investigated variables.

## Discussion

This study aims to investigate the interplay between POPU psychological stress, emotion dysregulation and insomnia symptoms during the second wave of the COVID-19 in Italy. We hypothesized that psychological stress and emotion dysregulation would play a mediating role in the relationship between POPU and insomnia symptoms. In particular, we expected that both psychological stress and emotion dysregulation would be associated to higher levels of insomnia symptoms mediating its association with POPU. In addition, given the documented negative implications of the COVID-

19 on several aspects of sleep quality,<sup>49</sup> we also examined the role of COVID-19 related variables. Surprisingly, no significant associations were found between COVID-19-related variables and insomnia symptoms, as well as, POPU, psychological stress, and emotion dysregulation. This result must be seen in light of the characteristics of the sample. In fact, the participants of this study were mostly indirectly affected by the COVID-19 pandemic. More specifically, about half of the participants reported having had a close one infected with SARS-CoV-2, while only a small minority was personally infected. It is possible that, due to the snowball sampling method used, people with more negative experiences with COVID-19 pandemic decided not to take part in the survey. Therefore, further research is needed on more representative samples.

As for the relationship between investigated variables and age, in line with the literature, we found that younger age was significantly and positively associated with higher psychological stress<sup>42</sup> and emotion dysregulation.<sup>50</sup> Indeed, the pandemic had a significant influence on mental health<sup>51,52</sup> with particularly marked consequences for some subcategories of the population, including young adults.<sup>53</sup> Among young adults, in fact, an increase in both internalizing (eg, withdrawal, somatic complaints, anxiety, and depression) and externalizing (eg, aggressive and rule-breaking behaviors) problems were found.<sup>54</sup> Consistent with previous study we also found that being female was significantly and positively associated with higher levels insomnia symptoms<sup>55</sup> and psychological stress.<sup>51</sup> Indeed, females were found to exhibit higher anxiety and perception of danger to the COVID-19 virus than males<sup>56</sup> and this could impact the sleep quality.<sup>57</sup> Furthermore, a significant and positive association between being male and POPU was shown, in line with previous research.<sup>16,58</sup>

Concerning our hypotheses, these have all been confirmed. As a result of the performed correlation analysis, a significant positive association was found between POPU and insomnia symptoms. This echoes previous evidence,<sup>18</sup> and is also in line with research into the broader dimension of problematic Internet use.<sup>59</sup> However, mediation analyses also highlighted that the relationship between POPU and insomnia symptoms occurs mainly through an indirect way, with the total mediation by psychological stress and emotion dysregulation.

Indeed, POPU was found to be associated with psychological stress and this corroborates previous studies that pointed out that not so much of the average daily use of pornography itself, but rather the levels of compulsiveness and perceived uncontrolled use are significantly associated with emotional distress,<sup>14,60</sup> with difficulty in controlling the use of pornography related to severe negative consequences.<sup>61</sup> Consistently, other research also showed that the problematic use of online sexual activities was associated with an increase in symptoms of anxiety, depression, and dissociation (see Hermand et al<sup>62</sup> for a review).

Furthermore, both POPU and psychological stress had a significant positive effect on emotion dysregulation. Individuals with POPU have in fact been described as having poor coping strategies and ineffective emotion regulation skills.<sup>60,63</sup> In this regard, although the literature highlights the etiological role of emotion dysregulation for both substance related<sup>64,65</sup> and behavioral addictions,<sup>64,66,67</sup> including the sexual one,<sup>68</sup> the data presented suggest that this can be further fueled by addictive behavior. The online pornography use can become problematic if used as a dysfunctional coping strategy for the regulation of affective states: this does not favor the development of more adaptive strategies in the subject, but on the contrary, stimulates a compulsive attitude towards cyberpornography feeding the state of dysregulation in the long term, in line with when the subject with sexual addiction is found.<sup>68,69</sup>

Finally, data showed that both psychological stress and emotion dysregulation were associated with greater insomnia symptoms, further supporting and enriching the associations highlighted in scientific literature concerning the impact of distress and arousal (see Bos and Macedo<sup>70</sup> for a review). Indeed, Tsypes et al<sup>71</sup> found that individuals with generalized anxiety disorder showed greater difficulties in emotion regulation, with a significant influence on a wide range of sleep problems. Parallely, previous research also highlighted that negative effects influenced sleep quality, both directly and indirectly through emotion dysregulation.<sup>72</sup>

Summing up, this study highlights a significant total effect of the POPU on insomnia symptoms which is mainly explained through an indirect path that involves the effects of psychological stress and emotion dysregulation. This appears particularly significant, especially in light of the effects that POPU (see Mauer-Vakil and Bahji<sup>73</sup> for a review), psychological stress,<sup>74</sup> emotion dysregulation,<sup>75</sup> and insomnia symptoms<sup>76</sup> may have on mental health. Furthermore,

these data appear particularly consistent and relevant also with respect to the current evidence related to the pandemic, which highlights high levels of POPU, psychological stress, emotion dysregulation, and insomnia symptoms.<sup>58,77–79</sup>

However, these findings have some limitations that should be noted. First, the cross-sectional nature of the study makes it impossible to draw inferences about causality in the associations between the variables. In fact, the mediation model was evoked based on theory, and it is not possible to rule out a reverse causation model in which increased insomnia symptoms generate psychological stress, emotion dysregulation and POPU. Therefore, we used the term “mediation” only in the statistical sense. Future research should use longitudinal designs to determine the direction of these associations. Furthermore, the use of a convenience snowball sample does not allow to calculate the response rate and the online diffusion of the survey limits our knowledge about participants' motivation to take part in the research. Thus, the generalizability of the findings is necessarily limited. Further studies with random or nationwide representative samples are warranted. Another limitation of this study includes using a sample with low levels of POPU and insomnia symptoms. However, our results are consistent with previous studies on POPU<sup>16</sup> and insomnia symptoms<sup>80</sup> conducted in the normal population. Further studies with clinical samples are needed to confirm and expand our findings.

Finally, the use of self-report measure exposes to the possibility of well-known biases (eg, the desirability one). The use of a multi-method technique for assessment and measurement (eg, integrating with interviews) could be an important goal for future research to overcome this issue.

## Conclusion

This study offered an in-depth exploration of the relationship between POPU and insomnia symptoms, showing the significant mediation role of psychological stress and emotion dysregulation. These data may have important practical implication and provided useful indication to elaborate effective clinical interventions. Indeed, these results enrich the framework of the negative consequences of POPU and underline the importance of working on this and its effects on psychological stress and emotion dysregulation to limit insomnia symptoms. In fact, our results suggest that taking into account negative consequences of POPU on users' psychological functioning could be more informative than solely screening for POPU (eg, by the use of criteria derived from substance use disorders). This process-based approach to clinical practice (eg, Kinderman et al<sup>81</sup>) may allow to avoid the overpathologization of a common behavior, such as online pornography use, and it may help clinicians to recognize psychological mechanisms underlying symptom presentation.

## Ethics Statement

All participants provided written informed consent and were informed about the purpose of the study. Data were collected and used complying with the Italian ethical standards and with the Declaration of Helsinki. The study was approved by the local ethics committee (CERIP – Comitato Etico del Centro di Ricerca e di Intervento Psicologico – University of Messina, prot. n. 17758) as the University of Parma's Research Ethics Board was not established yet at the time of project evaluation.

## Disclosure

Alessandro Musetti and Alessio Gori are co-first authors for this study. GP participated in advisory board for UCB Pharma, Jazz Pharmaceuticals, Bioproject, Takeda and Idorsia. The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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