





The Mediating Role of Emotion Dysregulation and Problematic Internet Use in the Relationship Between Negative Affect and Excessive Daytime Sleepiness: A Structural Equation Model

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Purpose: The present study aimed to explore the mediating role of emotion dysregulation and problematic Internet use in the relationship between negative affect and excessive daytime sleepiness.

Methods: This cross-sectional study included 664 Italian adults aged between 18 and 70 years ($M = 32.13$; $SD = 11.71$). Participants were asked to complete the Depression Anxiety Stress Scale, the Difficulties in Emotion Regulation Scale, the Compulsive Internet Use Scale-7, and the Epworth Sleepiness Scale to assess negative affect, emotion dysregulation, problematic internet use, and excessive daytime sleepiness, respectively.

Results: According to our results there are significant associations between negative affect, emotion dysregulation, problematic Internet use, and daytime sleepiness. Moreover, the structural equation model showed good fit indices. Emotion dysregulation and problematic Internet use partially mediated the relationship between negative mood and excessive daytime sleepiness.

Conclusion: By exploring the role of emotion dysregulation on the association between excessive daytime sleepiness and its possible predictors, our study might represent an important step toward the implementation of psychological intervention for reducing excessive daytime sleepiness. Emotion dysregulation appears to play a significant role in explaining the relationship between negative affect, problematic Internet use, and excessive daytime sleepiness. Thus, it should be considered a treatment target for reducing excessive daytime sleepiness.

Keywords: negative affect, psychological distress, excessive daytime sleepiness, emotion dysregulation, problematic Internet use

Introduction

Excessive daytime sleepiness (EDS) is one of the most major presenting sleep-related symptoms.¹ EDS refers to a set of symptoms that include unplanned daytime sleep, as well as the inability to remain alert or awake in passive situations,² resulting in an uncontrollable need to sleep and episodes of untimely sleep. EDS is the primary complaint of central disorders of hypersomnolence and is also a common symptom in both sleep apnea syndrome periodic limb movement disorder.^{2,3} Furthermore, EDS significantly impair patients' quality of life, physical functioning,^{4,5} psychological well-being^{5,6} and can disrupt social life⁷ and work performance.⁸

Several factors contribute to EDS, including inadequate nocturnal sleep, the presence of underlying sleep disorders such as obstructive sleep apnea, narcolepsy, or circadian rhythm disturbances,⁹ as well as mood disorders (such as depression and anxiety).¹⁰

Indeed, an increasing number of studies have highlighted associations between depression,^{8,11–14} anxiety,¹⁵ stress,¹⁶ and EDS. Interestingly, a recent longitudinal study found that depression and anxiety were significant predictive factors for EDS in a sample of women in the general population.¹⁷

A potential underlying mechanism of the association between negative mood (ie, depression, anxiety, and stress) and EDS^{8,11–16,18} might be emotion regulation. According to Gratz and Roemer,¹⁹ emotion regulation is defined as the ability to be aware of and accept emotions, to behave in accordance with personal goals even in the presence of negative emotions, while controlling impulsive behaviors. Whereas adaptive emotion regulation strategies play a protective role and can promote resilience against stressful life events,²⁰ on the contrary, dysfunctional emotion regulation is associated with several and significant forms of psychopathology.²¹ In this regard, given the association between negative mood and emotion dysregulation,²² it has been proposed that when functional emotion regulation strategies are lacking, experiencing negative affect (such as depression, anxiety, or stress) may lead to maladaptive behaviors, such as addictive behaviors.^{23,24}

Nowadays, one of the most common addictive behaviors correlated to EDS is problematic Internet use.

Problematic Internet use (PIU) is defined as excessive time spent in online activities and is often accompanied by uncontrolled preoccupation, stress and computer-related urges^{25,26} that could lead to psychological and physical health issue.^{26,27}

Evidence highlighted several psychological factors associated with PIU, such as personality features,²⁸ alexithymia²⁹ and poorer psychological health.³⁰ However, recently, emotional dysregulation has been suggested as a potential transdiagnostic factor underlying several psychopathological conditions^{31,32} including PIU.^{33,34} People with emotion regulation difficulties may engage in addictive behaviors in an attempt to minimize negative affect and emotional distress.^{34,35} In addition, PIU can be viewed as an “escape behavior” to cope with unpleasant feelings and emotions,^{36,37} aimed at alleviating negative moods.^{29,38} In line, one study found that individuals with PIU were more prone to suppressing and escaping their negative emotion engaging in PIU.³⁹

It has been well documented that the excessive use of Internet could lead to many adverse health^{40,41} and psychological consequences, as well as sleeping problems and sleep deprivation.⁴² Specifically, one of the most serious sleep problems related to PIU is EDS. In a recent cross-sectional study,⁴³ Demir et al found that PIU was an important factor that contributed to increasing the risk for EDS in a sample of University students. Generally, PIU is thought to lead to sleep deprivation. Indeed, it has been suggested that Internet use may cause a reduction in sleep duration^{44–46} and sleep onset difficulties,^{42,47} resulting in increased fatigue and sleepiness during the day.

The purpose of this study is to test the structural model, which was developed based on the literature to examine the relationships between negative affect, emotional dysregulation, PIU and EDS, as shown in [Figure 1](#).

Although the relationship between PIU and EDS has received increasing attention in the literature, most studies involved adolescent and young adult samples,^{43,48,49} while evidence in adults is limited.⁵⁰ Given these premises, the aim of the present study was to explore the relationship between negative affect and EDS, by assessing the mediating role of emotion dysregulation and PIU. We hypothesized that negative affect would be related to EDS and that this relationship would be partially and sequentially mediated by emotion dysregulation and PIU ([Figure 1](#)). Specifically, the hypotheses are the following:

H1: Negative affect levels would directly and positively affect emotional dysregulation levels.

H2: Emotional dysregulation levels would directly and positively affect PIU levels.

H3: PIU levels would directly and positively affect EDS levels.

H4: Negative affect levels would indirectly and positively affect EDS levels through emotional dysregulation and PIU.

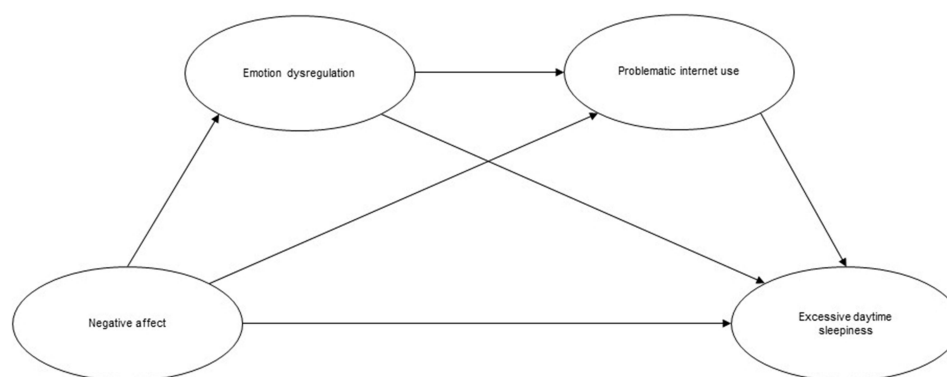


Figure 1 Hypothesized mediation model

Materials and Methods

Participants and Procedures

Data were collected from October to November 2020, during the COVID-19 pandemic. Participants were recruited from the general population via Internet announcements delivered on online platforms and social media. All participants were informed about the study and were asked to provide written informed consent. Participation in the study was entirely voluntary; participants were free to withdraw from the study at any time and did not receive any monetary compensation. All participants were asked to complete an online survey via an anonymous link. Uncompleted questionnaires were excluded from the data analysis. All procedures were carried out following the ethical standards of the Ethical Code of the Italian Association of Psychology (AIP), the European Code of Conduct for Research Integrity (ECCRI), the Helsinki Declaration of 1964, and its later advancements.

Measures

Demographical data were collected through a self-report form, while clinical factors were assessed using the following measures:

Negative affect. The Depression Anxiety Stress Scale (DASS-21)⁵¹ is a self-report questionnaire that assesses negative affect. The 21 items are rated on a 4-point Likert scale, ranging from 0 to 3. The DASS-21 is composed of three subscales: depression, anxiety, and stress. The total score ranges from 0 to 21, with higher scores indicating higher levels of negative affect. Scores <10 on the Depression subscale indicate normal levels of depression, while scores > 15 indicate moderate-to-severe levels of depression. Scores < 8 on the Anxiety subscale indicate normal levels of anxiety, while scores >8 indicate moderate-to-severe levels of depression. Scores < 15 on the Stress subscale indicate normal levels of stress, while scores > 15 indicate moderate-to-severe levels of stress. In our study, we used the Italian version⁵² which showed good psychometric properties (Cronbach's alpha values of subscales ranged from 0.83 to 0.91) in line with the original version.⁵¹ Cronbach's alpha in our sample was 0.92.

Emotional dysregulation. The Difficulties in Emotion Regulation Scale (DERS)¹⁹ is a self-report questionnaire used to assess emotion dysregulation. It consists of 36 items, rated on a 5-point Likert scale, ranging from 1 to 5, with higher scores suggesting greater difficulties in emotion regulation. The DERS is divided into six subscales: non-acceptance of negative emotions, inability to engage in purposeful behavior when experiencing negative emotions, difficulty controlling impulsive behavior when experiencing negative emotions, limited access to emotion regulation strategies that are considered effective, lack of awareness of emotions, and lack of understanding of the nature of emotions. The Italian version⁵³ showed good psychometric properties. Cronbach's alpha of the total score was 0.92. In our sample, Cronbach's alpha was 0.88.

Excessive daytime sleepiness. The Epworth Sleepiness Scale (ESS)⁵⁴ is a self-report questionnaire that assesses EDS. It is composed of 8 items ranging from 0 to 3 used. The total score ranges from 0 to 24 with higher scores

indicating higher levels of EDS. Specifically, EES scores from 11 to 12 indicate Mild EDS; EES scores ranged from 13 to 14 indicate Moderate EDS; EES scores ranged from 16 to 24 indicate Severe EDS. We used the Italian version⁵⁵ which showed good psychometric properties in line with the original version.⁵⁴ The Cronbach's alpha in our sample was 0.71.

Problematic Internet use. The Compulsive Internet Use Scale-7 (CIUS-7)⁵⁶ is a self-report questionnaire that assesses PIU. It comprises 7 items ranging from 0 to 4 with higher scores indicating greater PIU severity. We used the Italian version validated by Lopez et al.⁵⁷ In the current sample, Cronbach's alpha was 0.92.

Data Analytic Strategy

Descriptive statistics, including frequencies and percentages for categorical variables and means and standard deviations for continuous variables, were computed. Normality assumptions were tested by skewness and kurtosis coefficients. Correlations between all the continuous study variables were evaluated using Pearson's correlations.

Subsequently, a structural equation model (SEM) was used to test the relationships between negative affect, emotional dysregulation, PIU, and EDS using Robust Maximum Likelihood estimator (RML). Latent variables for PIU and EDS were computed using items as indicators, whereas the latent variable for emotion dysregulation was calculated using the DERS subscales. Similarly, for negative affect, we used the DASS-21 subscales.

The model's goodness of fit was evaluated using the root-mean-square error of approximation (RMSEA), the comparative fit index (CFI), and the standardized root-mean-square residual (SRMR). Hu and Bentler's goodness-of-fit criteria⁵⁸ were employed to indicate acceptable (CFI and Tucker–Lewis index [TLI] > 0.90, SRMR < 0.10, RMSEA < 0.08) and excellent fit (CFI and TLI > 0.95, SRMR < 0.08, RMSEA < 0.06).

Data were analyzed using IBM Statistical Package for the Social Sciences SPSS version 24 (Armonk, NY: IBM Corp) and Mplus software (version 8).

Results

Descriptive Characteristics of the Sample and Correlations Between All the Variables of the Study

This cross-sectional study included 664 Italian adults. The sample included 197 males (29.7%) and 467 females (70.3%). The mean age of the total sample was 32.13±11.71 years in a range between 18 and 70 years. Specifically, among male participants the mean age was 32.84±10.7 years in a range from a minimum of 18 to a maximum of 61 years. Among female participants the mean age was 31.82±12.11 years in an age range from a minimum of 18 to a maximum of 70 years. Among participants, 596 (70.64%) subjects reported no EDS, 68 (10.3%) showed moderate-to-severe levels of EDS. As for negative affect, 524 participants (78.8%) showed normal levels of depression and 140 (21.2%) reported moderate-to-severe levels of depression. Among participants, 539 subjects (81.1%) reported normal levels of anxiety and 125 (18.9%) showed moderate-to-severe levels of depression. Finally, 576 participants (86.6%) showed normal levels of stress while 88 participants (13.4%) reported moderate-to-severe levels of stress. Descriptive statistics of the sample are reported in [Table 1](#).

Pearson's correlations explored the relations between all the variables of interest. In general, we found significant associations between Negative affect (DASS-21), Emotion dysregulation (DERS), PIU (CIUS-7), and EDS (ESS). More specifically, all the subscales of the DASS-21 showed positive and significant correlations to each other and all the subscales of the DERS, with the only exception of the Awareness subscale, which showed no significant relations with the majority of other variables of the study. Similarly, all the subscales of the DASS-21 were significantly associated with most of the items of CIUS-7 and ESS with the only exception of the correlation between the Stress, Depression, and Anxiety subscales of the DASS-21 and items 2 and 8 of CIUS-7, and the correlation between the Stress subscale of the DASS-21 and item 3 of the CIUS-7.

The correlations between all the subscales of the DERS and the items of CIUS-7 were significant and positive, except for the Awareness subscale of the DERS which was related only to items 1 and 12 of the CIUS-7. The subscales of the

Table 1 Descriptive Statistics of the Sample and Main Measures Related to Negative Affect (DASS-21), Emotion Dysregulation (DERS), Problematic Internet Use (CIUS-7) and Daytime Sleepiness (EES)

Variables	N	F (%)	Min	Max	Mean	SD	Skewness	Kurtosis
Gender								
Males	197	197 (29.7)						
Females	467	467 (70.7)						
Age			18	70	32.13	11.710	0.625	-1.043
DASS-21								
Stress			0	21	7.70	5.549	0.589	-0.466
Anxiety			0	21	3.72	4.370	1.416	1.644
Depression			0	21	5.75	5.214	0.961	0.158
DASS-21 total score			0	63	17.17	13.781	0.891	0.142
DERS								
Non-Acceptance			6	30	13.36	5.912	0.849	-0.018
Goals			4	24	13.07	4.957	0.290	-0.669
Impulse			5	29	11.78	5.236	0.904	0.392
Awareness			0	24	9.51	5.197	0.293	-0.465
Strategies			7	39	17.12	7.070	0.929	0.392
Clarity			3	23	9.88	4.391	0.603	0.181
DERS total score			30	153	74.72	23.509	0.654	0.286
CIUS-7								
CIUS 1			0	4	1.36	1.139	0.509	-0.543
CIUS 3			0	4	0.79	1.047	1.302	0.943
CIUS 5			0	4	0.88	1.110	1.138	0.349
CIUS 7			0	4	0.48	0.879	2.038	3.806
CIUS 9			0	4	0.65	0.912	1.463	1.814
CIUS 11			0	4	0.50	0.874	1.956	3.608
CIUS 12			0	4	1.24	1.178	0.711	-0.344
CIUS total score			0	27	5.89	5.304	1.257	1.523
ESS								
ESS 1			0	3	0.72	0.862	1.019	0.223
ESS 2			0	3	1.55	0.944	0.004	-0.906
ESS 3			0	3	0.38	0.683	1.965	3.795
ESS 4			0	3	0.87	0.930	0.834	-0.242
ESS 5			0	3	1.73	0.941	-0.10	-0.982
ESS 6			0	3	0.10	0.394	4.436	21.55
ESS 7			0	3	0.75	0.873	0.965	0.067
ESS 8			0	3	0.12	0.436	4.025	17.41
EES total score			0	21	6.22	3.506	0.795	0.937

Abbreviations: SD, standard deviation; DASS-21, Depression Anxiety and Stress Scale; DERS, Difficulties in Emotion Regulation Scale; CIUS-7, Compulsive Internet Use Scale-7; ESS, Epworth Sleepiness Scale.

DERS were also significantly related to the items of ESS, except for the subscale Awareness of the DERS which was related only to items 4 and 5.

The items of CIUS-7 were all significantly related to the items of ESS, with the only exception for item 2 of the ESS which was unrelated to other items of CIUS-7.

Pearson's *r* correlations between all the variables of interest are reported in [Table 2](#).

The Structural Equation Model

We used a structural equation model to assess our hypothesis. The hypothesized model indicates that the positive relationships between negative affect (DASS-21) and EDS (ESS) would be sequentially and positively mediated by emotion dysregulation (DERS) and PIU (CIUS-7). The structural model is presented in [Figure 2](#); the results of the

Table 2 Correlations Between Negative Affect (DASS-21), Emotion Dysregulation (DERS), Problematic Internet Use (CIUS-7) and Daytime Sleepiness (EES)

	DASS-21	DERS	CIUS-7
DASS-21	–		
DERS	0.647**	–	
CIUS-7	0.453**	0.529**	–
EES	0.134*	0.188**	0.283**

Note: *p<0.01; **p<0.001.

Abbreviations: DASS-21, Depression Anxiety and Stress Scale; DERS, Difficulties in Emotion Regulation Scale; CIUS-7, Compulsive Internet Use Scale-7; ESS, Epworth Sleepiness Scale.

measurement model are presented in Table 3. Latent variables are depicted in circles, while rectangles represent measured variables.

To ensure model testing, items and scales that explained less than 10% of the variance of the latent variable were excluded.⁵⁹

Negative affect is a latent variable with three indicators represented by the three subscales of DASS21, namely Depression, Anxiety, and Stress. Similarly, emotion dysregulation is a latent variable, with five indicators that correspond to the five subscales of the DERS, namely, Non-Acceptance, Goals, Impulse, Strategies, Clarity.

According to our analyses, the subscale Awareness showed a low factor loading (–0.012), so it was excluded from the final model. However, this result was in line with other evidence.⁶⁰ EDS was a latent variable with 6 indicators: items 2 and 8 were excluded since the items showed low factor loadings. PIU was a latent variable with seven indicators that correspond to the items of the CIUS-7.

The model showed an acceptable goodness of fit with observed data, MLR $\chi^2 = 284.23$, $p < 0.001$; RMSEA = 0.034; 90% C.I [0.028–0.036], CFI = 0.85; SRMR = 0.03.

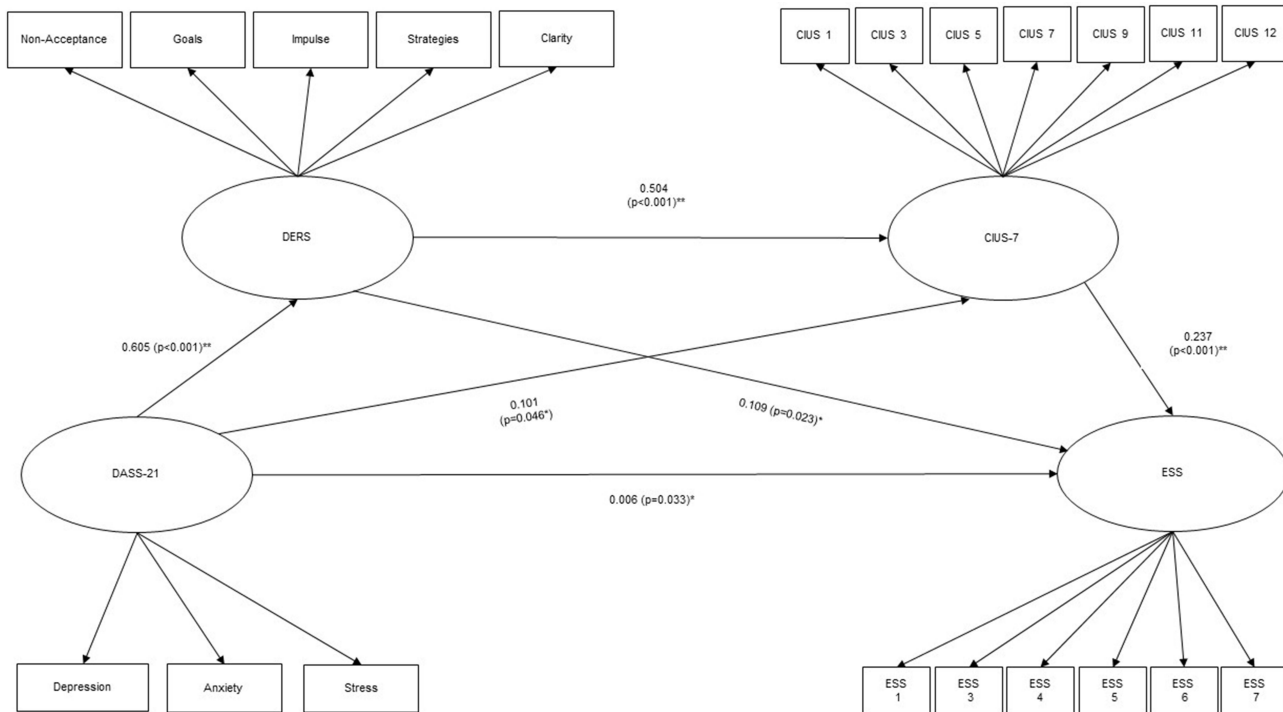


Figure 2 Standardized estimates of the mediation model.

Note: *p<0.05; **p<0.001.

Abbreviations: DASS, Depression Anxiety and Stress Scale; DERS, Difficulties in Emotion Regulation Strategies; CIUS-7, Compulsive Internet Use Scale; EES, Epworth Sleepiness Scale.

Table 3 Parameters of the Final Measurement Model

Construct	Observed Variables	Latent Variable Loadings	Cronbach's Alpha	Rho_A	Adjusted R ²
DASS-21	Stress Anxiety Depression	0.802 0.833 0.831	0.919	0.922	
DERS	Non-accept Goals Impulse Strategies Clarity	0.803 0.822 0.853 0.917 0.707	0.879	0.885	0.366
CIUS-7	CIUS 1 CIUS 3 CIUS 5 CIUS 7 CIUS 9 CIUS 11 CIUS 12	0.758 0.603 0.686 0.766 0.775 0.757 0.747	0.919	0.939	0.330
ESS	ESS 1 ESS 3 ESS 4 ESS 5 ESS 6 ESS 7	0.667 0.556 0.587 0.482 0.629 0.733	0.708	0.725	0.191

Abbreviations: DASS-21, Depression Anxiety and Stress Scale; DERS, Difficulties in Emotion Regulation Scale; CIUS-7, Compulsive Internet Use Scale-7; ESS, Epworth Sleepiness Scale.

The analysis of the modification indices identified that errors of the subscale Anxiety, Depression, and Stress of DASS and of items 1, 4, 6, and 7 of the ESS were correlated.

Since these variables examined highly related dimensions of the investigated constructs, their errors were allowed to covariate in the model ($r = 0.28$, $p < 0.001$ and $r = 0.90$, $p < 0.001$, for DASS subscales and ESS items, respectively). The full mediation model, including both the measurement and structural components, reported adequate indices of fit: MLR $\chi^2 = 536.50$, $p < 0.001$, RMSEA = 0.040, 90% C.I. [0.035–0.049], CFI = 0.93, SRMR = 0.03.

With regards to direct effects, the results indicated that higher levels of negative affect were directly associated with higher levels of emotion dysregulation and higher levels of PIU. Finally, higher levels of negative affect, higher levels of emotion dysregulation, and higher levels of PIU, were all associated with higher levels of EDS ($\beta = 0.061$; $p < 0.001$).

As for the indirect effects, the mediation path from negative affect to EDS through emotion dysregulation was significant, as well as the path including only PIU as a mediator. The full sequential mediation path, including both the emotion dysregulation and PIU as mediators, showed a small but significant indirect effect ($\beta = 0.072$; $p < 0.05$).

Discussion

EDS has been the focus of attention in recent years and has spurred research to identify its predictors and contributing factors. This study was conceived to explore the antecedents of EDS by assessing the relationship between negative affect, emotion dysregulation, PIU, and EDS in a sample of Italian adults from the general population. We hypothesized a significant mediating role of two-sequential mediators, emotional regulation and PIU, in the relationship between negative affect and EDS.

The results confirmed our hypothesis, showing significant associations in the expected direction between all the variables of interest. Specifically, we found a positive and significant association between negative affect and EDS. In

addition, we also found that this relationship was partially mediated by emotion dysregulation and Internet use sequentially.

Extensive evidence are in line with our findings about the association between negative affect and EDS.^{61–64} Specifically, Theorell-Haglöw et al found that depression and anxiety were significant predictors of EDS.⁶⁴ In line, also Smith et al, found that anxiety was a significant predictor of EDS.⁶⁵

Consistently with our hypothesized model, we found a positive and significant association between negative affect and emotion dysregulation, and between emotion dysregulation and EDS. These findings were in line with previous studies showing that negative affect and emotion dysregulation were related.²² Also, research has documented a strong relationship between emotions and sleep and has suggested that emotion regulation plays an important role in the interplay between negative mood or stress and sleep problems.⁶⁶

Our results showed a significant and positive association between negative affect and PIU, as well as between PIU and EDS. The positive association between negative affect and PIU is already reported in literature.⁶⁷ Indeed, previous evidence suggested that individuals with PIU were more likely to show negative affect⁶⁸ and sleep disturbances.⁶⁹

Similarly, as for the relation between PIU and EDS, we found additional evidence concerning the negative impact of maladaptive patterns of Internet use on sleep which was already described in literature^{70,71} In particular it has been previously reported that PIU is related to many sleep problems, including reduction in sleep duration,^{44–46} sleep onset difficulties,^{42,47} insomnia and EDS.⁷²

Our findings can be interpreted in light of the compensatory model of PIU.³⁴ There is a large body of literature suggesting that PIU can be interpreted as an “escape behavior”^{60,73,74} used to cope with distress and negative emotions in the absence of effective emotion regulation strategies.³⁶ Individuals with difficulties in emotion regulation and who experience negative emotional states might be more likely to increase regulatory behaviors, which in turn might result dysfunctional. This implies that PIU might be a dysfunctional emotional coping.^{60,75,76}

The current study presents important strengths, such as the consideration of a population on which the literature concerning EDS is scarce. Most previous evidence was collected in samples of young populations or clinical samples. On the contrary, in our study, we involved a non-clinical sample of Italian adult individuals from the general population. Nonetheless, the study comes with some limitations. Due to the cross-sectional design, causality could not be tested. Longitudinal studies should be done to overcome such a limitation. In addition, we involved a convenience sample of adults from the general population, and we used only self-report measures. Consequently, the results could not be extended to different samples and could be affected by biases. Moreover, in our study, we did not assess the level of exposure (for example, in terms of time spent engaging in Internet-based activities) to blue light-emitting devices, such as laptops, smartphones, and tablets. Evidence suggests that the use of these devices at bedtime has a negative effect on sleep^{77–79} and also impacts on melatonin secretion.⁴⁴ Thus, chronic and inappropriate-timed exposure to devices can disrupt the circadian clock^{80–82} eventually leading to sleep problems, which are common risk factors for EDS.^{83,84} Therefore, future research might consider also the role of blue-light emitting devices and their impact on sleep.

It is worth noting that the data collection for the present study has been carried out during the period of the second wave of COVID19 in Italy, which have had a strong negative impact on physical and psychological health of the Italian population, such as compromising psychological well-being, increasing depression, anxiety, stress, and reducing sleep quality, as we reported in our previous study.²² Thus, our results should be considered within the Covid-19 pandemic context, placing a limit on generalizability. Despite this, our results are still in line with the pre-Covid 19 literature.

Further replications and extensions of the study should be carried out in the future. Finally, replications in other clinical and non-clinical samples may contribute to the body of knowledge in the field.

Conclusions

According to our findings, there is a positive and significant association between negative affect and EDS. Also, we found that this relationship was partially and sequentially mediated by emotion dysregulation and PIU.

Our study might represent an important step toward the implementation of psychological intervention for reducing EDS. Since emotion dysregulation appears to play a significant role in explaining the relationship between negative affect, PIU, and EDS, the current evidence can be used to inform psychological interventions aimed to target emotion dysregulation for treating EDS. For example, future research may evaluate whether PIU and, in turn, EDS might be prevented by developing intervention aimed at improving emotion regulation skills.

Abbreviations

EDS, excessive daytime sleepiness; OSAS, obstructive sleep apnea syndrome; PLMD, periodic limb movement disorder; PIU, problematic Internet use; ADHD, attention deficit hyperactivity disorder; DASS, depression, anxiety, and stress scale; DERS, difficulties in emotion regulation scale; ESS, epworth sleepiness scale; CIUS, compulsive Internet use scale.

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. 12106) as the University of Parma's Research Ethics Board was not established yet at the time of project evaluation.

Disclosure

GP reports participating in advisory boards for and receiving personal fees from UCB Pharma, Jazz Pharmaceuticals, Bioproject, Takeda, and Idorsia, and reports no other potential conflicts of interest in this work. The remaining authors report no conflicts of interest in this work and 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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