Quality of life improvement in children with attention-deficit hyperactivity disorder reduces family’s strain: A structural equation model approach

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Abstract
Objectives: The objective of the study is to analyse how the quality of life of children diagnosed with attention-deficit/hyperactivity disorder (ADHD) impacts the relationship between disease severity and family burden.

Method: The data collected by a longitudinal, observational study involving 1478 children with ADHD residing in 10 European countries (aged 6 to 18 years) were analysed to evaluate the relationships between ADHD severity, the children’s quality of life and family burden.

Results: The disorder’s severity directly and indirectly affected the children’s health-related quality of life (HRQoL) and family burden. The degree of family burden was modulated by the children's HRQoL.

Conclusions: One of the primary causes of the stress experienced by parents of children with ADHD is their perception of the child’s reduced HRQoL and not the symptom severity itself. Efforts to minimize symptom severity cannot alone reduce family burden.

KEYWORDS
ADHD, children, family burden, health-related quality of life

1 | INTRODUCTION

Attention Deficit Hyperactivity disorder (ADHD) is one of the most common childhood neurobehavioural conditions (Boyle et al., 2011). ADHD symptoms usually become more evident in school-aged children, are more frequent in boys than in girls and tend to persist into adulthood (Centers for Disease Control and Prevention, 2013). The prevalence range reported is quite wide (from 0.2% to 34.5%), and heterogeneity in the methodological approaches used have contributed to these differences (Polanczyk et al., 2015). When case definition is based on a clinical evaluation, the overall ADHD prevalence is 2.9% (range: 1.1–16.7) (Reale & Bonati, 2018). The fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) (American Psychiatric Association, 2013) defines core ADHD symptoms as difficulty in paying attention, inability to focus and to control behaviour and being hyperactive. Symptoms such as these, which can only lead to a significant impairment at school (Spencer, 2006) and in the activities of daily life (Pineda et al., 1998),...
often persist into adolescence and adulthood, causing personal, social, occupational and even leisure time dysfunctions (Resnick, 2005).

According to the American Psychiatric Association, the severity of symptoms is pivotal for diagnosing and establishing the severity of the disorder (American Psychiatric Association, 2013). The clinical picture is frequently (in approximately 75% of cases) complicated by other mental disorders or multiple comorbid mental disorders (in approximately 60%) that adversely affect the prognosis and may necessitate specific therapeutic measures (Banaschewski et al., 2017). In short, ADHD symptoms result in a complex pattern of behaviours characterized by inattention and or impulsivity and hyperactivity leading to increased demands on parents’ time and contributing to their level of stress (Heath et al., 2014). Although families of children with ADHD usually face more challenging caregiver situations, their children's difficult behaviours may undermine parents' confidence and well-being with respect to their caregiving role (Counts et al., 2005).

Several studies have confirmed that ADHD severity has an important impact on family strain (Breen & Barkley, 1988; Harrison & Sofronoff, 2002; Mash & Johnston, 1983). A significant positive correlation was found between the severity of the disorder, measured using the Children’s Global Assessment Scale (CGAS) scores, and parent’s stress scores, measured using the Parenting Stress Index Short Form (PSI-SF) (Narkunam et al., 2014). The findings emerging when instruments other than the PSI-SF were used (Johnson & Reader, 2002) likewise suggest that an optimal management of a child diagnosed with ADHD requires more than just minimizing the core symptoms; other interventions, for both the child and the parents, are needed to reduce family burden (Narkunam et al., 2014).

It has been found that health-related quality of life (HRQoL) is lower in ADHD children compared with that in healthy children (Danckaerts et al., 2010), and the same has been reported for the members of their families (Dey et al., 2019). The severity of the symptoms may increase the impact of ADHD on the children's HRQoL and family distress (Cappe et al., 2017). Treatments (pharmacological and/or psychological) may have a positive effect, even if it may be only short lived and negligible, on HRQoL of both children and parents (Bundgaard Larsen et al., 2020; Coghill, 2010).

The current study set out to analyse the data of a longitudinal observational multi-country study focusing on children with ADHD in the attempt to evaluate the association between the symptom severity, the HRQoL of the children and the family burden.

We hypothesized that children's HRQoL can mediate the impact of ADHD severity on family burden.

2 | METHODS

2.1 | Participants and procedure

We submitted a research proposal through the Clinical Study Data Request (CSDR) website (https://clinicalstudydatarequest.com) to gain access to the original data sets of the ADHD Observational Research in Europe (ADORE) project (Ralston & Lorenzo, 2004), a prospective, non-interventional study involving 1478 children with hyperactive/inattentive/impulsive symptoms but not yet formally diagnosed with ADHD. The children were observed by 244 investigators residing in 10 European countries: Austria, Denmark, France, Germany, Iceland, Italy, the Netherlands, Norway, Switzerland and the United Kingdom. Patient recruitment was begun in June 2003 and completed in December 2004. After submitting a signed data sharing agreement, we were furnished with access to anonymized patient-level data and supporting documentation in a secure data access system, known as the SAS Clinical Trial Data Transparency system.

2.2 | Measures

2.2.1 | Time lived in the disorder

Children with ADHD symptomatology who had never been formally diagnosed with the disorder were eligible to participate in the study. As symptoms can arise at different ages, time of onset might influence their severity and therefore the children’s quality of life. The time lived in with the disorder was defined as the length of time between the onset of the first symptoms and enrolment in the study.

2.2.2 | Treatment

The children with more severe symptoms were receiving pharmacological; psychological; occupational; or speech therapy, educational interventions in school, psychomotor/physiotherapy or herb/homoeopathy; some were being taught relaxation techniques or were undergoing electroencephalogram biofeedback or hypnosis; others were simply following a diet. Treatment variable was dichotomized as received (at least one type) and not received (none).

2.2.3 | Severity and impairment

The evaluation of the children with ADHD took into consideration a wide range of factors in the attempt to establish a

Key messages

- The symptoms of children with attention-deficit/hyperactivity disorder (ADHD) dynamically contribute to generating high levels of distress in their parents.
- The parents’ emotional distress can be explained by multiplicity of factors, including symptom severity.
- A sizable part of family strain is attributable to the child’s health-related quality of life (HRQoL).
- Some interventions should be designed to alleviate parents’ burden.
The CGAS, a numeric scale used by clinicians to rate the general functioning of a child. Scores range from 1 (most impaired) to 100 (best level of adaptive functioning) (Kraočvil et al., 2007; Schaffer et al., 1983). A CGAS score of >70 is generally accepted to indicate good overall functioning and a score of <60 indicates poor functioning that will generally require intervention;

- The Clinical Global Impression-Severity (CGI-S) scale, another numeric scale used by clinicians to learn more about the patient's global functioning. Scores range from 1 (normal, not at all ill) to 7 (very severely ill) (Busner & Targum, 2007). A score of 4 indicates moderately ill and a score of 5 indicates markedly ill;

- The ADHD Rating Scale IV Edition (ADHD-RS-IV) is a validated instrument to assess ADHD symptoms; each of its 18 items corresponds to one of the items on the Diagnostic and Statistical Manual of Mental Disorders, IV edition (DSM-IV) diagnostic criteria (DuPaul et al., 1998). The patient's parent responds to the scale's items during a semi-structured interview with a clinician. Severity is rated on a 4-point Likert scale ranging from 0 (never or rarely) to 3 (very often), with higher scores indicative of greater ADHD-related behaviour;

- The parent-reported version of the Strengths and Difficulties Questionnaire (SDQ) (Goodman, 1997), a brief psychopathology screening tool that consists of 25 items regarding five subscales: emotional symptoms, conduct problems, hyperactivity-inattention, peer relationship problems and prosocial behaviour. Only the hyperactivity-inattention subscale was considered in the present study. A score <6 identifies ‘normal’ subjects;

- The patient's comorbidities were also investigated. The pathologies considered were anxiety, asthma, bipolar disorder, conduct disorder, coordination problems, depression, epilepsy, learning disorder, obsessive compulsive disorder, oppositional defiant disorder, psychosis, tics and Tourette's syndrome. For anxiety, depression, conduct disorder and oppositional defiant disorder, the investigator was requested to assess severity in single-item questions in Likert scale format; for other problems, the investigator was requested to simply state if the problem is present in single-item questions (Ralston & Lorenzo, 2004). Comorbidity variable was defined as the number of comorbid disorders reported by the investigator.

These five scores were transformed into dichotomous variables using validated cut-offs (CGAS ≤ 40: serious/severe problems; CGI ≥ 5: markedly ill or worse; number of comorbidities ≥ 1; ADHD-RS-IV ≥ 41; SDQ-hyperactivity≥8). (Döpfner et al., 2006; Overgaard et al., 2019; Reale et al., 2017) and then they were used to define the ‘child's severity and impairment’ latent factor. Higher scores in ‘child's severity and impairment’ latent factor indicate more severe health conditions.

2.2.4 Quality of life

Children's HRQoL was assessed using the Standard Parent Report Form of the Child Health and Illness Profile-Child Edition (CHIP-CE). The 76 items on the questionnaire examine all aspects of a child's life and primarily his/her family and school life that could affect his/her HRQoL (Riley et al., 2006).

The scores on the five domains (i.e., satisfaction, comfort, resilience, risk avoidance and achievement), which range from 0 (worst) to 5 (best), were used to measure the ‘Quality of life’ factor. Higher scores indicate better quality of life.

2.2.5 Family strain

The stress and pressure on the parents and families of ADHD children were assessed using the Family Strain Index (FSI). The FSI includes two ‘emotional’ items, which measure the affective and emotional stress associated with being a caregiver of a child with ADHD, and four ‘restriction’ items, assessing those limitations in the family's social activities resulting from living with a child with this disorder (Riley et al., 2006). Parents were asked to rate the frequency of each item over the past four weeks on a 5-point Likert scale: 0 (never), 1 (almost never), 2 (sometimes), 3 (almost always) and 4 (always). A total score was obtained by summing the scores of the six items (possible range 0–24); higher scores indicate more emotional distress or interruption of normal activities due to the child's problems.

2.3 Data analysis

The social, demographic and clinical variables were summarized using descriptive statistics: categorical variables are presented as percentages; continuous variables as mean and standard deviation (SD) or median and interquartile range (IQR), according to the normality assumption, which was tested using the Shapiro–Wilks test.

Pearson's correlation was calculated to verify the association between the five variables considered to assess ADHD severity and impairment: CGAS, CGI-S, ADHD-RS-IV and SDQ scores, as well as the number of comorbidities.

A structural equation model (SEM) approach was used to examine the relationships between family strain; the child's severity/impairment and quality of life; and the effect of the child's sex, treatment and time lived in the disorder. The hypothesized relationships are represented in Figure 1. Observed variables are indicated by squares, latent variables by circles and effects by arrows. The observed variables of CGAS, CGI, ADHD-RS-IV, comorbidities and SDQ contributed to the latent construct ‘Child's severity and impairment’; the scores on the five CHIP-CE domains (i.e., satisfaction, comfort, resilience, risk avoidance and achievement) defined the latent construct ‘child's quality of life’.

Missing data were imputed using the full information maximum likelihood method of the CALIS procedure (Yung & Zhang, 2011),
which has been shown to be superior to ad hoc methods for treating incomplete observations (Muthén et al., 1987) for both normal (Enders & Bandalos, 2001) and nonnormal distributions (Enders, 2001).

The following goodness-of-fit indices and thresholds were used: the standardized root mean square residual (SRMS, <0.08), the root mean square error of approximation (RMSEA, <0.08) and the goodness of fit index (GFI, ≥0.90). All analyses were performed using SAS version 9.4.

3 | RESULTS

The sociodemographic characteristics of the 1478 children with ADHD who participated in the study are outlined in Table 1. The majority of the participants were male (84.10%) and between the ages of 6 and 9 (67.13%) years. The age of the child when his/her parents first became aware of the hyperactive/inattentive symptoms/problems was younger than 5 years for 44.58% of the participants.

The mean scores on the subscales of the CHIP-CE score range between 2.9 (achievement domain) and 4.0 (comfort domain), showing a deviation from a standard population, while the mean FSI score was 10.4 (SD = 5.4), indicating a moderate level of emotional distress or interruption of normal activities due to the child's problems. The mean CGAS score was 55.2 (SD = 10.6), indicating that the child's functioning was variable and that there were sporadic difficulties or symptoms in several but not all social areas. The mean CGI score was 4.4 (SD = 0.9), denoting overt symptoms causing noticeable, but modest, functional impairment or distress; the symptom level probably warranted medication.

The CGAS and CGI scores were significantly correlated to one another (r = −0.537) and to the number of comorbidities, the ADHD-RS-IV score and the SDQ hyperactivity score, with Pearson's coefficients falling into the low to moderate range (absolute values between 0.274 and 0.382) (Table 2).

The standardized structural coefficients of the model depicted in Figure 1 are presented in Table 3. A good model-data fit was found (SRMSR = 0.0498, RMSEA = 0.0824 and GFI = 0.9307).

Data analysis uncovered that symptom severity was influenced by both the time lived in the disorder and the treatment utilized. The longer a child lived with the disorder, in fact, the more his/her symptoms worsened. Moreover, the children with more severe symptoms had a higher probability of receiving some treatment or therapy, which did not, however, significantly improve their quality of life. Treatment had only an indirect effect on the children's HRQoL, which was mediated by symptom severity. The children who received treatment of some kind were those who displayed more severe symptoms and therefore whose HRQoL was lower.

The severity of symptoms and impairments strongly affected the life of the whole family: the symptom severity produced the strongest observed effect on the child's quality of life (−0.7530) and a direct and indirect effect on family strain. The family's burden increased proportionally with the worsening of symptoms (total effect = 0.6273), primarily due to the mediating effect of the child's quality of life (indirect effect = 0.4339). The finding suggests that the stress experienced by parents is mainly caused by their perception of their child's reduced quality of life rather than by symptom severity itself.

4 | DISCUSSION

The aim of this study was to investigate the interrelationships between the severity of the symptoms of ADHD, the child's HRQoL and family burden. Some studies have reported that the severity of a
child’s ADHD symptoms and the parents’ perception of his/her impairment across emotional, cognitive and behavioural domains are a source of anxiety for them (Graziano et al., 2011). The current study set out to investigate these variables in the effort to gain greater insight into the causes and effects of the child’s HRQoL and family burden.

As expected (Reale et al., 2017), ADHD severity and impairment were found to be key factors affecting the children and their families’ lives. Indeed, in agreement with previous investigations, the findings of the present study strongly suggest that worse symptoms were associated, on the one hand, with worse HRQoL (Coghill & Hodgkins, 2016; Klassen et al., 2004) and, on the other, with higher parenting stress (Cappe et al., 2017; Muñoz-Silva et al., 2017).

The model used here made it possible to confirm these direct effects of ADHD severity and impairment as well as to identify its indirect effect on family burden. Indeed, what emerged was the mediating role of the children’s HRQoL, which in turn negatively affected parental stress.

This result highlights the parents’ growing perception of their children’s low HRQoL and of their own helplessness and sense of loss.

| TABLE 1 | Participant characteristics |
|---------|----------------------------|
| % of sample | N |
| Age at baseline, years | |
| 6-9 | 67.13 |
| 10-12 | 22.00 |
| 13-17 | 10.87 |
| Age at first awareness, years | |
| 0-4 | 44.58 |
| 5-6 | 30.15 |
| 7-9 | 19.70 |
| 10-17 | 5.57 |
| Prescribed pharmacotherapy (yes) | 3.26 |
| Prescribed psychotherapy (yes) | 18.37 |
| Other prescribed treatment (yes) | 43.79 |
| Sex (male) | 84.10 |

| Median [IQR] | [Range] | N |
|--------------|---------|---|
| CGAS | 55.0 [11.0] | 1206 |
| CGI | 4.0 [1.0] | 1472 |
| Number of comorbidities | 3.0 [2.0] | 1473 |
| ADHD-RS | 36.0 [13.0] | 1476 |
| SDQ | 9.0 [3.0] | 1459 |
| CHIP-CE: satisfaction domain | 3.6 [0.8] | 1464 |
| CHIP-CE: comfort domain | 4.0 [0.6] | 1463 |
| CHIP-CE: resilience domain | 3.7 [0.6] | 1467 |
| CHIP-CE: risk avoidance domain | 3.6 [0.9] | 1462 |
| CHIP-CE: achievement domain | 2.9 [0.8] | 1414 |
| Family strain (FSI) | 10.0 [8.0] | 1444 |

| Abbreviations: ADHD-RS, attention-deficit/hyperactivity disorder Rating Scale; CGAS, Children’s Global Assessment Scale; CGI, clinical global impression; CHIP-SE, Child Health and Illness Profile-Child Edition; FSI, Family Strain Index; IQR, interquartile range; SDQ, Strengths and Difficulties Questionnaire. |

| TABLE 2 | Pearson’s correlation between the five indices (CGAS, CGI, number of comorbidities, ADHD-RS-IV and SDQ) considered to assess ADHD severity and impairment |
|---------|---------------------------------------------------------------|
| CGAS | | CGI | | Number of comorbidities | | ADHD-RS-IV | | SDQ |
| CGAS | | | | | | | | |
| CGI | | | | | | | | |
| Number of comorbidities | | | | | | | | |
| ADHD-RS-IV | | | | | | | | |
| SDQ | | | | | | | | |

| Abbreviations: ADHD-RS-IV, attention-deficit/hyperactivity disorder Rating Scale IV Edition; CGAS, Children’s Global Assessment Scale; CGI, clinical global impression; SDQ, Strengths and Difficulties Questionnaire. |

| TABLE 3 | Standardized estimated parameters for the structural model: direct, indirect and total effects |
|---------|---------------------------------------------------------------|
| Effects on child’s severity | Direct | Indirect | Total |
| Time lived in the disorder | 0.1114 * | – | 0.1114 * |
| Treatment/therapy | 0.1123 * | – | 0.1123 * |
| Sex | 0.0264 | – | 0.0264 |

| Effects on child’s QoL | Direct | Indirect | Total |
| Child’s severity | –0.7530 * | – | –0.7530 * |
| Time lived in the disorder | –0.1006 * | –0.0838 * | –0.1844 |
| Treatment/therapy | 0.0416 | –0.0846 * | –0.0430 |
| Sex | 0.0046 | –0.0198 | –0.0152 |

| Effects on family’s strain | Direct | Indirect | Total |
| Child’s QoL | –0.5763 * | – | –0.5763 * |
| Child’s severity | 0.1934 * | 0.4339 * | 0.6273 * |
| Time lived in the disorder | –0.0057 | 0.1278 * | 0.1221 * |
| Treatment/therapy | –0.0481 * | 0.0465 | –0.0016 |
| Sex | 0.0163 | 0.0139 | 0.0302 |

| Abbreviation: QoL, quality of life. |
| *p < 0.0001. |
In the light of these findings, it is clear that health care systems should invest in programmes aiming not only to reduce symptom severity in children diagnosed with ADHD but also to improve their well-being and quality of life. The efficacy of pharmacological treatments in managing ADHD core symptoms has long been recognized (Kaplan & Sadock, 1988), and some psychosocial interventions have recently proven to be effective. Parent training programmes could also help to teach parents how to manage their children’s challenging behaviours (Bundgaard Larsen et al., 2020; Coates et al., 2015; Zwi et al., 2011). The present study found that psychosocial measures had only scarce effects on the HRQoL of ADHD patients (Danckaerts et al., 2010; Kousha & Abbasi Kakrodi, 2019) and medication also had a limited effect (Coghill & Hodgkins, 2016). In fact, some treatments had only a weak, indirect effect on the HRQoL.

Long-term comparative studies have investigated a variety of pharmacological and/or nonpharmacological treatments utilized to aid ADHD children manage their behaviour and parents deal with their stress. Further studies are necessary to identify what characteristics, besides symptom severity, are usually found in the patients who benefit from those treatments.

### 4.1 Limitations and strengths

The study presents some limitations. First, data regarding some parameters were missing, although for a small proportion of patients, which has not introduced bias thanks to the estimation method adopted. Second, the contribution of each participating country was different and not proportional to the target national population. This implies that our findings refer to a general European population of 6–17 years old ADHD patients and their families.

As far as its strengths are concerned, the study examined the data of a sizable number of patients, and it used a large battery of well-known, reliable scales/questionnaires to evaluate the patients’ neuropsychiatric status. The consistency and reliability of the ADOR data set used in the present work have, moreover, been assessed by several studies. (Döpfner et al., 2006; Ralston & Lorenzo, 2004).

The impact that ADHD and its severity has on the children and their parents’ well-being warrants further study. Efforts in any case to help these families need to be two sided: the children require help to manage their symptoms and the parents need to learn better parenting skills and perhaps even more importantly to deal with their feelings of guilt and anxiety.

### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are not publicly available but can be requested from the Clinical Study Data Request (CSDR) website (https://clinicalstudydatarequest.com). To obtain access to anonymized patient-level data and supporting documentation in a secure data access system, it is necessary to submit a research proposal and sign a data sharing agreement.

### FUNDING INFORMATION

This work was supported by the European Commission through the Horizon 2020 Framework (grant agreement number 634201). The sole responsibility for the content of this project lies with the authors. It does not necessarily reflect the opinion of the EU. The European Commission is not responsible for any use that may be made of the information contained therein.

### CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

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How to cite this article: Rocco, I, Bonati, M, Corso, B, Minicuci, N. Quality of life improvement in children with attention-deficit hyperactivity disorder reduces family’s strain: A structural equation model approach. Child Care Health Dev. 2021; 47:667–674. https://doi.org/10.1111/cch.12874