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Measuring positive mental health in children with attention-deficit/hyperactive disorder

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Given the importance and prevalence of Attention-Deficit/Hyperactive Disorder (ADHD), numerous studies have focused on relevant psychopathological symptoms. Although ADHD has a negative impact on various core domains of children's well-being, research regarding the disorder's effects on positive mental health has been more limited. This pathological view is partial and should be completed with a positive perspective. For this reason, the main objective of the present research is to apply a model that integrates both perspectives, the Two-continua Model of Mental Health, to a sample of children diagnosed with ADHD. As expected, Parallel Analysis and Exploratory Factor Analysis indicated that two different unipolar correlated dimensions emerged from the presence of symptoms of psychopathology (i.e., inattention and hyperactivity/impulsivity) and the presence of symptoms of positive mental health (i.e., hedonic well-being, psychological well-being, and social well-being). ADHD symptoms correlated significantly with psychological and social well-being but not with hedonic well-being indicators. As a conclusion, to accurately assess the mental health of children with ADHD, evaluation protocols should include both psychopathology and well-being measures.

Attention deficit disorder, with or without hyperactivity (ADHD), is one of the most common neurodevelopmental disorders, with prevalence in children from 6 to 7%, out of which 65% continue to have symptoms and neuropsychological deficits into adulthood¹. According to the DSM-5², the main symptoms of ADHD are linked to inattention (11 symptoms) and hyperactivity/impulsivity (9 symptoms). The previous diagnostic differentiation between subtypes proposed by the DSM-IV³ has been criticized for its lack of stability in children and for its diagnostic accuracy⁴. Therefore, subtypes have been replaced in the DSM-5² by "presentations" in an attempt to reflect that symptoms are often fluid within individuals across their lifespan rather than stable traits⁵. Specifically, a distinction is made among ADHD predominantly characterized by inattention (presence of six or more of the 11 symptoms), ADHD predominantly hyperactive/impulsive (presence of six or more of the 9 symptoms), and mixed ADHD (both criteria are met); there is also a category of partial remission³.

Given the prevalence of ADHD and its impact on children's mental health⁶, numerous studies have been conducted in recent years regarding this disorder, although most research has employed a pathological perspective. Literature related to clinical assessment of ADHD in children indicates that evaluation should primarily rely on interviewing the parents about existing problems, and analyzing in detail the child's developmental history, including medical and psychiatric background, information about family functioning, peer relationships, and school history⁷. To assess the child's mental state, employing a semi-structured standardized clinical interview that includes assessments of ADHD symptoms is recommended⁸. The assessment should cover difficulties and strengths in various important domains, such as school, peer/friend relationships, or family relationships. Third-party informant-based scales for ADHD assessment (e.g., parents or teachers), such as the ADHD Rating Scale-IV (ADHD RS-IV)^{9,10} or the Conners' Rating Scales¹¹, are also excellent diagnostic tools but should not be the only source of information¹². Lastly, an additional interview should be conducted with the child or adolescent to gain insight into the patient's perspective on current problems, needs, and goals¹³. Although children and adolescents are the best informants of their subjective experience (a core aspect when assessing quality of life), they tend to underestimate some clinically relevant behaviors (e.g., excessive fidgeting, being easily distracted by irrelevant stimuli). Moreover, they tend to overestimate their competencies (i.e., positive illusionary bias)^{14,15}. For these reasons, parents and teachers are considered optimal informants, and self-reported scales have lower ADHD diagnostic validity¹⁶.

The symptoms of ADHD have a negative impact on various aspects of individuals' lives, particularly affecting children in educational and social domains, both within the family and with peers¹⁷. For these reasons, assessing

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children's well-being is crucial, regardless of their psychopathological assessment^{18,19}. In fact, health not only implies the absence of disease but also the presence of a state of complete physical, mental, and social well-being²⁰. Therefore, to have a complete picture of mental health in children with ADHD, the pathological perspective must be completed with a positive perspective. Although there are different theories that integrate both views (e.g., Salutogenesis Model of Antonovsky²¹, probably the model most widely used and with more empirical evidence is the Complete State Model of Health (CSMH) developed by Corey Keyes²²⁻²⁶. Importantly, in contrast to previous models that consider positive health and illness as the opposite poles of a single continuum (univariate bipolar models²⁷, the CSMH posits that positive health and illness are two correlated unipolar dimensions. For this reason, this model is also known as the Two-continua Model of Mental Health²⁴. This bivariate unipolar conception is especially relevant to study the mental health of children with ADHD because the presence of pathology does not necessarily imply the absence of positive health. Although the CSMH has been widely applied in both adult and children's populations^{24,25}, the existence of two distinct axes (mental illness - positive mental health) must be tested for each disorder²⁵, because in some of them the bidimensionality axiom is not satisfied (e.g., depression²⁸).

Despite the plausible relevance of the CSMH in the study of ADHD, to the best of our knowledge, there is no previous study examining the existence of the bidimensionality of positive mental health and psychopathology in this disorder. Therefore, the primary objective of the present research is to apply the CSMH to a sample of children diagnosed with ADHD. Our second objective is to examine the relationship between ADHD and positive health indicators as distinct yet related constructs. Finally, although direct well-being measures in children and adolescents have numerous advantages, these instruments present two significant limitations²⁹: sensitivity to individual differences (e.g., differences in introspective capacity³⁰ and risk of fakeability (e.g., children could hide or conceal their internal state³¹. For these reasons, our third objective is to develop a new semi-structured interview to assess the presence of positive health in children with ADHD symptoms based on the CSMH. Regarding our hypothesis, according to the CSMH we expect that two distinct but correlated unipolar dimensions will emerge from the measures used to assess ADHD and positive health indicators (i.e., well-being indicators).

Methods

Participants

To test our main hypothesis, we will conduct an exploratory factor analysis (EFA). Determining the minimal sample size required to achieve a proper solution in the EFA is a complex problem^{32,33} and different recommendations have been proposed in the literature. The cases-per-variable ratio has been considered one of the best options in terms of the stability and accuracy of the EFA solution³⁴. For this reason, to determine the sample size we employed a conservative cases-per-variable ratio of 25-to-1³⁵. Taking into account that in our study five variables will be introduced in the EFA, we collected one hundred and twenty-five children. One participant did not complete the study and was excluded. Children are between 8 and 18 years old (8_{years} n = 13; 9_{years} n = 13; 10_{years} n = 14; 11_{years} n = 2; 12_{years} n = 14; 13_{years} n = 21; 14_{years} n = 5; 15_{years} n = 18; 16_{years} n = 7; 17_{years} n = 5; 18_{years} n = 12). Ninety participants were male (72,58%) and thirty-four were female (37,42%) with a mean age of 12.72 years (SD = 3.11). Participants were recruited through an invitation letter explaining the nature of the project, which was sent to members of the AMHIDA (Asociación Manchega de Personas con Hyperactividad y/o Deficit de Atención; Manchegan Association of People with Hyperactivity with/without Attention Deficit) in Castilla La Mancha. Participants had to meet the following inclusion criteria: (1) Having a clinical diagnosis of ADHD using the Structured Clinical Interview for DSM-5-Clinician Version (SCID-5-CV)³⁶, (2) Being between the ages of 8 and 18, (3) Receiving psychological treatment for at least one year. Participants with a comorbid diagnosis of other mental disorders at the time the study was conducted were excluded (e.g., Major Depressive Disorder). In addition, participants were excluded if they did not complete all the questionnaires. For participants under the legal age, informed consent was completed by their legal representatives and both participants and legal representatives were informed about the study. Adults completed the informed consent themselves. The consent form explicitly stated that non-participation in the study would not affect the services provided by the AMHIDA psychological clinic. Participants did not receive any compensation for completing the study.

Procedure

Participants completed the study as part of the psychological care protocol of the AMHIDA association between October 2021 and October 2022. All families were informed that the collected data would be confidential and anonymous. This study was approved by the Ethics Committee of the General University Hospital of Ciudad Real - University of Castilla la Mancha. The data collection process involved three interviews. In the first interview, detailed information about the study was presented, questions from the family and participants were answered, and the informed consent was signed if they agreed to participate. The inclusion criteria were also verified during this interview. In the second interview, assessment instruments were administered. Finally, in the last interview, family members were informed about the study results, thanked, and debriefed.

Measures

Attention deficit hyperactivity disorder

The ADHD-RS-IV^{9,10} is a brief behavioral questionnaire designed to detect symptoms of inattention and hyperactivity/impulsivity in children aged 5 to 18 years, based on reports from parents or teachers. The instrument consists of a total of 18 items that align with the ADHD symptoms in the DSM-IV³, similar to those in the current DSM-5². The proposed bifactorial structure of Inattention (IA) and Hyperactivity/Impulsivity (HI) subscales (9 items per scale) with a second-order general factor has been confirmed in various studies conducted in different languages, such as Spanish³⁷. Family members and a clinical psychologist specialized in

ADHD completed each item using a 4-point Likert scale with scores ranging from 0 (never/rarely) to 3 (very often). Disagreements regarding any items were resolved through discussion. Consequently, total scores on the ADHD-RS range from 0 to 54, with higher scores indicating more ADHD symptoms. Using ROC curve analyses Vallejo-Valdivieso and colleagues³⁷ propose a cut-off point of 17 to discriminate between patients with and without ADHD in the Spanish population (91.9% sensitivity, 90.3% specificity). Although all participants in our study had an ADHD diagnosis, 10 of them scored lower than 17. Therefore, in this study, the ADHD-RS demonstrated a sensitivity of 91.94%. Notably, the ADHD-RS-IV was used instead of the ADHD-RS-5 because the Spanish version of the latter is not currently validated, and the symptoms listed in the scale did not change between the two DSM versions. The Spanish version of the ADHD-RS-IV is published in the journal *Neurología*³⁷ and available for free use. In the present study, the Cronbach's alpha coefficient for the ADHD-RS-IV was 0.87 (IA subscale $\alpha=0.82$; HI subscale $\alpha=0.86$).

Well-being

To measure well-being, we employed the Mental Health Continuum Short Form (MHC-SF)³⁸ questionnaire. This instrument consists of 14 items assessing hedonic-emotional well-being (HWB; 3 items) -a perspective focusing on pleasure and happiness- and eudaimonic well-being (11 items) -that is centered on life meaning and self-realization. Eudaimonic well-being is decomposed in psychological well-being (PWB; 6 items), and social well-being (SoWB; 5 items). The items correspond to each of the dimensions guided by the theory. For example, the item "In the past month, how often did you feel happy" evaluates children with ADHD positive affect, one of the dimensions of hedonic well-being. The item "In the past month, how often did you feel like you belonged to a community (such as a social group, your neighborhood, your city)?" evaluates social integration (social well-being), a critical dimension of eudaimonic well-being in children with ADHD. In previous research, the instrument demonstrated excellent internal consistency and factorial validity in Spanish samples³⁹. Participants responded to the items using a 6-point Likert scale, with scores ranging from 1 (never) to 6 (every day). Consequently, total scores on the MHC-SF range from 14 to 84, with higher scores indicating higher levels of well-being. Additionally, scores for the three subscales, HWB, PWB, and SoWB, were calculated. The Spanish version of the MHC-SF is published in the journal *Psicothema*³⁹ and is available for free use. In the present study, the Cronbach's alpha coefficient for the MHC-SF was 0.90 (HWB $\alpha=0.65$; PWB $\alpha=0.63$, and SoWB $\alpha=0.64$). Following Keyes²² a categorical diagnosis of the presence of mental health was also obtained. To do so, each patient participated in a semi-structured interview based on the symptoms proposed by Keyes²² (positive affect, life satisfaction, autonomy, self-acceptance, positive relationships, environmental mastery, purpose in life, personal growth, social acceptance, social actualization, social contribution, social coherence and social integration). A clinical psychologist specialized in positive psychology interviewed the patients and coded the presence or absence of each symptom. Examples of the questions used in the semi-structured interview for each symptom are provided in the Supplementary Material. The presence of positive mental health requires both criteria of *hedonia* (at least one of the symptoms 1–2) and *positive functioning* (at least six of the symptoms 3–13) to be met (CSMH categorical diagnosis; see Supplementary Material)²².

Data analysis

To examine the relationships between all variables, Pearson correlations were employed. Next, to test if the Two-continua Model of Mental Health can be applied to the study of ADHD, we examined whether a bi-factorial model emerges from the measures used to assess both well-being and ADHD symptomatology. To do it, we conducted an exploratory factor analysis (EFA) and computed the Kaiser-Meyer Olkin (KMO) test and Bartlett's test of sphericity to confirm the adequacy of the matrix. An important decision linked to the emergence of a bi-factorial model is the number of factors to maintain in the EFA. We conducted a Parallel Analysis (PA) because it is one of the most accurate factor retention methods⁴⁰. Based on the results of the PA, we conducted an EFA with Factor program 10.10.03 edition⁴¹. As factor extraction method, we used robust unweighted least squares, and as rotation method, direct oblimin, since prior research found moderate correlations between psychopathological symptoms and well-being²⁵. Finally, to compute the robust goodness-of fit indices of the model, we employed an Exploratory Structural Equation Modeling (EFA-SEM or ESEM) approach⁴² with Factor program 10.10.03.

Results

The means, standard deviations, skewness, kurtosis, and Pearson's correlation coefficients of all the instruments used in the study are presented in Table 1. Skewness values ranged from -0.82 to -0.03, and kurtosis values ranged from -0.91 to 0.68. According to criteria set in previous literature (values ranged between -2 and 2 for skewness, and -7 and 7 for kurtosis⁴³, all variables in the study followed a normal distribution. As in previous research, the subscales of the MHC-SF showed significant correlations among each other³⁸, as did the subscales of the ADHD-RS^{9,10}. More important for the purpose of the present research, the correlation between psychopathology (ADHD-RS) and well-being (MHC-SF) was significant, although relatively weak, indicating that there is no overlap between constructs. This result suggests that ADHD and positive mental health could be two different yet related dimensions, and not two poles of a single continuum, as suggested by the Two-continua Model of Mental Health. Importantly, a closer examination of the relationship between the well-being subscales and the ADHD-RS reveals that HWB was not significantly related to the ADHD scale and subscales, while PWB and SoWB were negatively correlated with these psychopathology measures. This suggests that ADHD is less related to hedonic indicators and more to eudaimonic indicators.

To test our main hypothesis, the existence of bidimensionality ADHD - Positive Mental Health, we conducted an Exploratory Factor Analysis (EFA). Kaiser-Meyer-Olkin (KMO) value (0.66) and Bartlett's test of sphericity ($\chi^2=353.1, p<.000$) suggested that EFA is adequate for this sample. The Mardia multivariate skewness and kurtosis coefficients were 10.10 and 47.70, respectively, indicating a non-normal multivariate distribution.

	Mean	S.D.	Skewness	Kurtosis	2	3	4	5	6	7
1. Hedonic well-being	14.65	2.65	-0.81	-0.05	0.66**	0.55**	0.80**	-0.09	-0.10	-0.12
2. Psychological Well-being	30.04	3.84	-0.67	0.11		0.70**	0.91**	-0.18*	-0.15	-0.20*
3. Social Well-being	24.13	3.88	-0.81	0.68			0.88**	-0.22*	-0.17	-0.23**
4. Mental health continuum SF	68.83	9.11	-0.82	0.56				-0.20*	-0.16	-0.21*
5. Inattention Scale	15.85	5.35	-0.15	-0.91					.41**	.82**
6. Hyperactivity/impulsivity	13.95	5.81	-0.21	-0.50						.85**
7. ADHD rating scale	29.81	9.38	-0.03	-0.77						

Table 1. Means, standard deviation (S.D.), skewness, kurtosis and Pearson's correlations for well-being scales and ADHD scales.

	Factor 1	Factor 2
Hedonic Well-being	-0.01	0.60
Psychological Well-being	0.04	0.94
Social Well-being	-0.07	0.74
Inattention	0.85	0.01
Hyperactivity/Impulsivity	0.48	-0.03
% Variance	46.73	24.89

Table 2. Factor analysis for well-being scales and ADHD scales. Note. The factorial matrix obtained through a robust extraction method using unweighted least squares with direct oblimin rotation is displayed. Values exceeding 0.40 are highlighted in bold.

	ADHD		
	Presence ADHD Rating Scale > 17	Absence ADHD Rating Scale \leq 17	Total
Positive Mental Health			
Presence	102	10	112
Absence	12	0	12
Total	114	10	

Table 3. Contingency table of presence/absence of ADHD based on the ADHD rating scale and presence/absence of positive mental health according to the complete state model of health. Pearson's $\chi^2 = 1.17$ $p = .28$. Fisher's exact test $p = .60$.

For this reason, in the EFA we employed robust unweighted least squares. According to the Parallel Analysis (PA), only two factors were retained because only the first two eigenvalues of the real dataset (i.e., 2.34; 1.24) exceeded mean (i.e., 1.40; 1.19) and 95th percentile random values (i.e., 1.25; 1.11). Following the PA criterion, we introduced five variables in the EFA: HWB, PWB, SoWB, IA, and HI (Table 2). The $N: p$ ratio was 24.8, higher than the one recommended in previous literature to achieve a good factorial recovery⁴⁴. The two ADHD-RS subscales primarily loaded on the first factor (46.73% of explained variance), while the MHC-SF subscales loaded on the second factor (24.89% of explained variance). These results indicate the likely existence of a bifactorial model of mental health: mental illness (ADHD-RS; factor 1) and positive mental health (MHC-SF). The correlation between both factors was -0.28, an indicator of the existing relationship between mental illness and positive mental health. Finally, using an ESEM approach⁴² we computed the robust goodness-of-fit indices of the proposed model. In this sense, the bifactorial model showed an excellent fit to the data ($\chi^2 = 0.70$, $df = 1$, $CFI = 0.99$, $AGFI = 0.98$, $RMSEA = 0.01$).

Once the hypothesis of bidimensionality was tested, our next objective was to evaluate whether children with ADHD could be considered as healthy when meeting the diagnostic criteria for positive mental health (categorical diagnostic approach). The categorical diagnosis requires meeting the criterion of hedonia (at least one of the two symptoms of positive affect or life satisfaction) and the criterion of positive functioning (at least six symptoms of psychological well-being and social well-being). Twelve participants did not meet the diagnostic criteria for positive mental health. Therefore, 112 participants had positive mental health despite having a diagnosis of ADHD. Considering the cut-off score proposed by Vallejo-Valdivieso et al.³⁷ for the ADHD-RS scale, 10 participants would not meet the criteria for ADHD according to psychometric criteria. For this reason, we calculated a contingency table of positive mental health (presence or absence) versus ADHD (presence or absence according to the ADHD-RS cut-off score) (Table 3). To examine the relationship between the variables, we computed a Fisher's exact test because some of the expected values in the contingency cells were less than 5. The results indicated that the two variables were not related (Fisher's exact test, $p = .54$).

Discussion

ADHD is one of the most common disorders in school-age children¹. The set of symptoms associated with ADHD, hyperactive behavior, impulsivity, and inability to maintain attention, significantly affect psychological functioning in academic, social, and family domains⁴. For these reasons, it is especially relevant to develop clinical assessment protocols to evaluate children's well-being suffering from this disorder. As the World Health Organization (WHO) suggests, health is not only the absence of illness but also the presence of a state of complete physical, mental, and social well-being²⁰. One of the most widely used models to assess the presence of positive mental health is the Two-continua Model of Mental Health^{22,23}.

In the present research, we applied the Two-continua Model of Mental Health to the study of ADHD. As hypothesized, our results suggest that two distinct correlated dimensions emerge from the presence of symptoms of psychopathology (i.e., inattention and hyperactivity/impulsivity) and the presence of symptoms of positive mental health (i.e., Hedonic Well-being, Psychological Well-being, and Social Well-being). The results of the EFA indicate that ADHD measures load on a first factor (i.e., Psychopathology) and well-being measures primarily load on a second factor (i.e., Positive Mental Health). Therefore, the presence/absence of psychopathology does not imply the presence/absence of positive health. In other words, both constructs are different, although they are related. As a consequence of this bidimensionality, to properly assess the health of children with ADHD, we cannot solely rely on measures of psychopathology but must also include measures of well-being and quality of life within the assessment protocols. Although there are no previous studies applying the MECS to the study of ADHD, these results are consistent with those found in other studies using distinct theoretical models about the relationship between quality of life and symptom severity. For example, in a comprehensive review, Danckaerts and colleagues⁴⁵ indicate that well-being measures and severity of ADHD symptoms correlate moderately and significantly.

In our study, the total score of the ADHD-RS scale correlated significantly with psychological and social well-being indicators and with the MHC-SF total score. The higher the symptoms of ADHD, the lower the levels of these positive mental health indicators, thus replicating previous research⁴⁵. Specifically, these results indicate the significant impact that ADHD has on patients' eudaimonic well-being. In this sense, one of the dimensions of psychological well-being that may be most affected is self-acceptance. Previous studies have found that ADHD decreases patients' self-esteem which is a key element of self-acceptance⁴⁶. Finally, the impact of ADHD on social well-being can also be very significant. Children with ADHD experience greater difficulties in their social relationships with school peers and with their family members⁴⁷, which affect social integration, a key indicator of social well-being. In fact, they are more likely to experience bullying⁴⁸.

However, our results did not show a significant relation between ADHD and hedonic well-being. Although these results were not expected, there are other studies with similar findings⁴⁹. One possible explanation is that hedonic (vs. psychological and social) well-being is of a more subjective nature. In this sense, regarding the assessment of positive mental health using the MHC-SF, the values of Hedonic Well-being (BH), Psychological Well-being (BP), and Social Well-being (BSO) in the children of our study do not seem to differ from values in children from the general Spanish or Portuguese population^{50,51}. These results also replicate those found in the few studies conducted in children with ADHD using self-reported quality of life assessment instruments, such as the Child Health Questionnaire-Child Form (CHQ-CF87)⁵². In these studies, children with ADHD report similar well-being and quality of life scores as healthy controls or the general population.

Although children and adolescents are the best informants of their subjective experience, well-being self-reported measures have important limitations. For example, they are sensitive to individual differences in self-awareness (i.e., to the fact that people differ significantly in their ability to be aware of their own opinions and internal states⁵³, and this limitation is especially relevant in children, because they have a limited capacity for introspection³¹. Moreover, they are susceptible to so-called response factors⁵⁴. These factors are problematic because they can lead children to bias their true internal states, even if they know them accurately. In this sense, adolescents with ADHD tend to overestimate their competencies (i.e., positive illusionary bias)^{14,15}.

For this reason, another objective of our study was to develop a semi-structured interview to make a categorical diagnosis of children with ADHD well-being using the MECS as a theoretical framework. The results of the interview indicated that 112 out of 124 children were diagnosed as having positive mental health. Although this result may be unexpected, we must consider that the sample of our study consisted of children who had been undergoing psychological treatment for at least one year, and it's plausible to think that this treatment improved their well-being levels. Therefore, the semi-structured interview and the MHC-SF probably reflected this improvement. In this sense, the fact that all participants were receiving treatment could be considered a limitation of the study, and it would be interesting for future studies to compare children with ADHD who received treatment with those who did not.

Despite the importance of our results, the present study has more limitations. First, the representativeness of the sample (e.g., all participants were recruited in the same patients' association) may limit the generalization of the results. A second limitation is the lack of longitudinal measures. We couldn't employ pre-post treatment due to the dynamics of functioning in the AMHIDA psychological clinic since children arrive with an initial baseline treatment. It would be important to study the effect of psychological and pharmaceutical treatments on well-being classical measures and on the new semi-structured interview. In this sense, we believe that this new measure, based on the MECS, could be a reliable and sensitive measure of change, and therefore should be able to capture changes in well-being and quality of life after treatment in future longitudinal studies. In fact, this is a common limitation in literature of ADHD. Despite their relevance, there are very few longitudinal studies on the effectiveness of psychological and pharmacological treatments on children with ADHD well-being⁴⁵. Another limitation of our study is that we did not perform a Confirmatory Factor Analyses. As previously mentioned, to the best of our knowledge, there is no previous research examining the existence of two distinct axes (mental illness - positive mental health) in ADHD. For this reason, although we had a hypothesis about the factorial

structure based on the CSMH, we couldn't make a strong assumption about how many factors might exist. For these reasons we consider that EFA was the best approach, following by a complementary Exploratory Structural Equation Modelling approach to test the model fit.

Data availability

The clinical datasets generated during and/or analyzed during the current study are not available due to privacy or ethical restrictions. However, data files are available from the corresponding author on reasonable request. Please contact Miriam Bajo at miriam.bajo@uclm.es to request access to these data.

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Author contributions

All authors contributed to the study conception and design. Material preparation and data collection were performed by JRG. Data analyses were performed by MB, DD, MS and RGM. The first draft of the manuscript was written by MB, JRG, DD and MS, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Declarations

Competing interests

The authors declare no competing interests.

Ethical approval

The study was approved by the ethics committee of the “Universidad de Castilla - La Mancha” (UCLM) and the Hospital General Universitario de Ciudad Real (“Comité Ético de Investigación Clínica HGUCR-UCLM”, No. 01/2020/C-305). It was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Additional information

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