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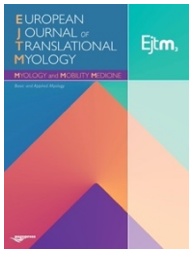

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Lessons from the pandemic era: do we need new strategies to improve conservative treatment adherence in adolescent idiopathic scoliosis? A retrospective analysis

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Abstract

This study aims to examine whether the COVID-19 pandemic affected the adherence to conservative AIS treatment. Adolescent Idiopathic Scoliosis (AIS) is characterized by a lateral curvature of the spine of at least 10 degrees. Compliance rates in conservative treatments are influenced by various factors. From a database of AIS patients, we selected 30 AIS patients who were assessed before, during, and after the COVID-19 pandemic. Data regarding Cobb's angle, brace prescription, prescribed brace wear time, brace wear compliance, and time dedicated to sports activities were collected over a six-year period from January 2018 to December 2023, divided into three 2-year time periods (before, during, and after COVID-19). There was an increased percentage of AIS patients prescribed with a brace during the pandemic. However, no significant differences in Cobb's angle were observed. Additionally, the prescribed wear time showed a significant decrease from the pre-COVID period to the post-COVID period (p-value = 0.03). Wear compliance exhibited a decreasing trend from pre- to during- and post-COVID-19 periods without reaching statistically significant differences, and the time dedicated to sports statistically significantly decreased. These differences were statistically significant when comparing the pre- vs. post- and pre- vs. during-COVID-19 periods (p-values 0.01, 0.04, respectively). Our study highlights changes in AIS conservative treatment during and after the COVID-19 pandemic. The increase in the number of patients prescribed with a brace during the pandemic, although not supported by an increase in Cobb's angle, may be attributed to the concerns about regular monitoring during the reduction of rehabilitation services. The observed decreases in brace compliance and involvement in sport activities, which persisted even in the post-pandemic period,

emphasizes the lasting impact of the pandemic on AIS management, necessitating innovative approaches to address these ongoing concerns.

Key words: rehabilitation; scoliosis; pandemic; brace; sport.

Introduction

Adolescent Idiopathic Scoliosis (AIS) is characterized by a lateral curvature of the spine, typically measured using Cobb's angle, of at least 10 degrees, and a rotation of vertebral bodies.[1,2] This condition is prevalent among adolescents in the early stages of puberty, impacting approximately 1–4% of this population, with a higher occurrence in young women.[3,4]

The etiology of scoliosis remains partially unknown, with various factors contributing to its development.[5-10]

The management of AIS currently range from close observation and monitoring to the prescription of orthotic braces, exercise regimens, and, in severe cases, surgical intervention.[11] The primary goals of conservative treatment for AIS patients include potentially reducing curve progression during puberty, preventing or addressing respiratory dysfunction, managing spinal pain syndromes, and enhancing aesthetics through postural correction.[1,10-13] Observation is initially recommended, in conjunction with regular radiographic assessments typically every 6–12 months, to monitor curve progression until skeletal maturity.[11,14] If the curve reaches 25° Cobb angle, braces may be considered to prevent further spine deformity, while surgical spinal fusion becomes an option for curves exceeding 40° Cobb angle.[1,3,10,11] The success of brace treatment for AIS patients depends on various factors, including the severity of the curvature, the age of the patient, the type of scoliotic curve, and, most importantly, compliance. As a matter of fact, previous studies report that bracing is more effective if the actual wear time is at least 12-16 hours a day compared to a wearing time of less than 12 hours a day.[15] However, poor orthosis compliance, ranging from 33% to 75% of the prescribed wear time, is commonly reported, which can significantly impact the effectiveness of treatment.[16-18] Compliance rates in scoliosis brace treatment are influenced by various factors, including patients' mental and physical conditions, brace design, patient age, and psychological factors.[16,19,20]

Exercise is also generally encouraged and considered safe for AIS patients, even though the role of physical activity in AIS conservative treatment represents a complex challenge.[21]

The COVID-19 pandemic, caused by the novel coronavirus SARS-CoV-2, has determined significant changes in all the fields of medicine, including the conservative management of AIS.[22,23] Social distancing measures limited access to physical therapy sessions and scheduled follow-up appointments, potentially affecting the continuity of conservative treatment plans.[23,24] Furthermore, during the pandemic, concerns and psychological issues may have influenced adherence to conservative treatment.[25-27] Nevertheless, evidence of changes in treatment adherence is still scarce in the literature.

Our study aims to examine changes in adherence to AIS brace treatment during the COVID-19 pandemic period by comparing data reported in three time periods, each lasting two years: before the onset of the COVID-19 pandemic, during its global spread, and after the emergency ended, when isolation measures became less stringent. We also evaluated engagement in sports activities during these three time periods, as we expected this to decrease during the pandemic period and therefore wanted to have a comparison that increased the coherence and consistency of our results.

Materials and Methods

Study population

This retrospective study reviewed a database of AIS patients evaluated in the outpatient setting of the Rehabilitation Unit of the University Hospital in Padova, Italy, between January 2018 and December 2023.

Inclusion criteria considered adolescent individuals of both genders with AIS, as defined by the criteria established by the SRS (presence of a Cobb angle of at least 10° on anteroposterior standing spine radiographs), from 13 to 18 years. Patients included in the study were required to have participated in at least one assessment during each of the three periods considered (24 months before the COVID-19 pandemic, during the pandemic, and after the COVID-19 containment measures were reduced). Only patients who received conservative treatment without surgery and started wearing a brace for the first time during the observation period were included in the study. The patients included in the study did not change the type of brace worn during the observation periods.

Individuals outside the specified age range, those diagnosed with conditions other than AIS, individuals with a prior history of scoliosis surgery or brace wearing, and those with incomplete or insufficient medical records were excluded.

Data collection

During outpatient assessments, demographic data were collected, including the subjects' gender, age in months, family history of scoliosis, radiographic Cobb angle measurement, and estimation of skeletal maturity by Risser sign. Additionally, detailed records were taken to assess the prescription of brace treatment (yes or no) and compliance with brace treatment, calculated as a percentage of the prescribed hours the brace was worn. The study also documented the number of hours per week dedicated to sports activities.
Only data collected during in-person visits were considered even during the COVID-19 emergency.

Statistical analysis and methodology

We analyzed data from patients that were evaluated in all three of the following time periods: i) pre COVID-19: from January 2018 to December 2019; ii) during COVID-19: this wording indicates the maximum peak period of the pandemic, from January 2020 to December 2021. This time period was characterized by stringent isolation measures after COVID-19 was declared as a pandemic by the World Health Organization on March 11, 2020; iii) after COVID-19: this wording indicates the period from January 1, 2022, to December 31, 2023. During this period, the emergency measures were progressively lifted as the end of the COVID-19 state of emergency in Italy was declared on March 31, 2022.
The statistical analysis was conducted using the Non Parametric Combination (NPC) Methodology.[28] This permutation-based technique is a distribution-free methodology since it does not require any distributional assumptions. One advantage of the NPC methodology is that it does not require any normality assumptions, unlike other commonly used parametric tests like the t-test. It can be successfully applied to both numerical and categorical variables, both in case of paired samples and repeated measurements. Furthermore, NPC can be applied to data with a small sample size or in the presence of missing values - as is commonly the case in observational prospective studies. Therefore, we chose to apply this methodology to our database of paired samples (*i.e.* data from repeated visits of the same patient), in which some of the variables had missing data. For example, the Cobb's angle, which can only be assessed through radiographs, is not typically repeated at every visit. Finally, it is a flexible methodology which allows us to consider the most suitable system of hypotheses according to the nature of the problem. In our case, it allowed us to consider the appropriate one-sided alternative in accordance with our beliefs about the data. The only requirements of the NPC methodology are the exchangeability property under the null hypothesis, which is verified by our dataset. In more detail, a data sample is deemed exchangeable if its joint probability

distribution remains unchanged after permutation. In simpler terms, shuffling the data under the null hypothesis does not alter the joint probability of the sample. See Winkler *et al.* (2014) for a detailed and visual explanation of this concept.[29]

Let us consider our dataset characterized by 30 patients who visited our facility before, during and after COVID-19 pandemic. Our aim is to assess if there is statistically significant difference in the mean values of a number of variables of interest between two of the three distinct periods considered in our analysis, i.e. before and during the COVID-19 pandemic, during and after the COVID-19 pandemic, and before and after the COVID-19 pandemic.

Before entering in a detailed description of how NPC methodology works, let us focus on defining the main notations of this technique. Let us consider our *p*-dimensional dataset $Y = Y_N^{(j)}$ characterized by *p* variables of interest *j*=1:*p* and sample size equals to *a* (*N*=1:*a*).

For each of the *p*-variables considered in our problem, the NPC requires us to define an appropriate system of hypotheses. In our particular case, we consider the equality of mean values as statistic test for each $j = 1,\ldots,p$ in two different period of times t1 vs. t2 (*i.e.*, pre COVID-19 vs. during COVID-19; during COVI-19 vs. post COVID-19; and pre COVID-19 vs. post COVID-19):

$$H_{0,j}: \mu_j^{(t1)} = \mu_j^{(t2)}, \forall\, j = 1, \ldots, p$$

For what concerns the alternative hypothesis, NPC has the advantage to deal with both two-sided and one-sided order alternatives. Thus, according to the relationship we want to analyze, we consider one of these two alternatives. In particular, our focus will be on one-sided order alternatives.

To understand how the NPC works, let now focus on one of our p variables (*i.e.*, the prescribed wear time).

First, the NPC computes our chosen test statistic (equality of mean values) and provides our observed test statistic $T^{(O)}$ evaluated on our initial dataset.

At this point, we permute the observations of our variable by applying a random sign and then we applied again the test statistic to obtain our permuted test statistic T_1.

We repeat this step B times to obtain our vector of permuted test statistics $T_1, \ldots, T_b, \ldots, T_B$.

To retrieve our p-value we retrieve centered empirical cumulative function $L^*\left(T^{(O)}\right)$:

$$L^*(t) = \frac{\frac{1}{2} + \frac{1}{2}\sum_{b=1}^{B} I(T_b = t) + \sum_{b=1}^{B} I(T_b > t)}{B + 1}$$

Which essentially counts how many times the permuted test statistics $T_1, \dots, T_b, \dots, T_B$ are equal or greater than our observed test statistic $T^{(O)}$ and divides it for the number of permutation plus one.

A multiplicity adjustment (*i.e.,* the Bonferroni correction)[28] is then applied to our p-value λ to obtain the adjusted p-value $\tilde{\lambda}$. The decision of the data is finally made using the adjusted p-value.

Results

Demographic characteristics

From our database of 580 individuals, 30 subjects were identified who were evaluated during all three time periods of interest. The age of the subjects ranged from 13 to 18 years with a mean value of 16.96 years. A substantial proportion of the sample was female (76.67%), whereas 23.34% were male.

Among this population, 7 of 30 patients did not present familiarity with scoliosis (23.34%), 8 reported a paternal family history of scoliosis (26.67%), while 14 out of 30 (46.67%) reported a maternal family history.

The majority of the sample (70%) exhibited a Risser sign 0 at the first visit.

The radiographic Cobb angle at the first visit ranged from 14° to 50°, with a mean value of 30°.

Brace compliance

The NPC methodology described in the previous paragraph was employed to identify statistical differences among the variables of interest between the "pre COVID-19" and "post COVID-19" time periods, between the "pre COVID-19" and "during COVID-19" time periods, and "during COVID-19" and "post COVID-19" time periods, separately. Variables of interest were: Cobb's angle, hump, brace wear prescription, prescribed brace wear time, brace wear compliance, time dedicated to sport activities.

The percentage of individuals being prescribed a brace was 73.34% (22 out of 30) pre COVID-19. This percentage increased to approximately 86.67% (26 out of 30) during COVID-19, and decreased to 66.67% (20 out of 30) after COVID-19. Nevertheless, the statistical analysis did not reveal any significant differences (p-values were 0.90, 0.58, and 0.31 pre *vs*. post, pre *vs*. during, and during *vs*. post COVID-19, respectively).

An initial decrease in Cobb's angle during the COVID-19 period (mean = 25.31°) compared to the pre COVID-19 period (mean = 29.38°), followed by an increase in the post COVID-19 period (mean = 29.70°) was observed. However, statistical analysis did not reveal any significant differences (p-values are 0.45, 0.46, and 0.49 for the variations in Cobb's angle pre vs. post, pre vs. during, and during vs. post COVID-19, respectively).
Interestingly, prescribed wear time decreased between the pre- (22.07±2.19) and the post- (18.62±5.92) COVID-19 period, as well as between pre- and during (21.25) COVID-19, and between during and post COVID-19 (Figure 1). The p-values reached statistical significance for the comparison between pre- and post- COVID-19 (p-value = 0.03) but not between between during- and post- COVID-19 (p-value = 0.07), and between pre- and during COVID-19 (p-value = 0.34). A correlation analysis revealed a significant negative correlation (-0.52) between the age of the sample and the prescribed wear time, indicating that as the age of the sample increased, the prescribed wear time tended to decrease.
Wear compliance showed a decreasing trend from the pre- (mean = 82.8%) to the during (mean = 78.96%) and to the post- (mean = 75.83%) COVID-19 periods (Figure 2). Nevertheless, the statistical analysis does not reveal any significant differences (p-values are 0.81, 0.31, and 0.74 for pre- vs. post-, pre- vs. during, and during vs. post-COVID-19, respectively)

Sport activities engagement

As indicated in the graph, the time dedicated to sport decreased from the pre COVID-19 period (mean = 2.8 hours) to during COVID-19 (mean 0.99 hours) and post-COVID-19 (mean = 0.77 hours). These differences were statistically significant when comparing the pre- *vs*. post- and pre *vs*. during COVID-19 periods (p-values 0.01, 0.04, respectively) (Figure 3).

Discussion

The use of brace treatment is typically recommended for treatment of AIS for curves between 25° and 40° with remaining growth (Risser stage 0–3).[11,30] Compliance with this treatment is considered among the most important prognostic factors for successful results.[30] However, poor compliance with bracing is widely reported due to discomfort and restriction of movement.[18,31-33] Emotional discomfort and effects on quality of life have also been indicated as critical factors for compliance.[34-35]
Our analysis assessed changes in adherence to brace treatment and sport activities over a six-year time span from 2018 and 2023, when varying levels of isolation measures due to

COVID-19 pandemic were in place. The study was conducted by selecting data from patients who had attended outpatient clinics for AIS in the two years prior, during the peak pandemic years, and in the two subsequent years at a center in the Veneto region of Italy. This region experienced widespread dissemination of the pandemic among the population, resulting in stringent lockdown and isolation measures.

In our research, rather than employing a parametric statistical approach, we opted for the use of a permutation-based technique to analyze changes in adherence from before to during and after COVID-19. In particular, we considered the partial p-values obtained through the application of the NPC methodology since it has proven successful in analyzing data from similar observational studies in previous work.[36] In addition, this type of statistical test is particularly suited for our analysis because it does not require verification of distributional assumptions, can be applied to both numerical and binary variables, and is well applicable to data with missing values.[37] Using this approach, our study observed an initial increase in orthotic prescriptions during the COVID-19 era, followed by a subsequent decrease in the post-COVID period. On one hand, this increase can be explained by the rise in age and consequently the greater need for intervention during the pubertal period, as also confirmed by our data showing that as age increased and, therefore, once the pubertal growth spurt was surpassed, brace wearing time prescription decreased. On the other hand, the rise in brace prescriptions did not correlate with an increase in Cobb angle during the pandemic period. In fact, quite the opposite, the Cobb angle often showed a decrease compared to the previous radiographic assessment. Hence, it is plausible to hypothesize that during the pandemic, due to concerns about the regular monitoring of spinal deformity progression, early introduction of part-time brace usage was favored. This decision may have also been influenced by the limited access to rehabilitative services and therapeutic exercise programs during the pandemic.[38]

So far, only one study has investigated brace treatment adherence during the pandemic, reporting an increased abandonment rates during the first wave of Covid-19, consisting in the period between March and September 2020.[27] Also in our study, the trend in brace wear compliance showed a decline from the pre-COVID period to the during-COVID period and further into the post-COVID period. While the increased availability of time and reduced conflicts with other activities during confinement could potentially facilitate brace adherence, the deterioration of adolescents' psycho-emotional state due to disrupted routines and limited social interactions likely had a negative impact on compliance.[39-43] Furthermore, the

pandemic resulted in limited access to healthcare services, leading to disruptions in in-person follow-ups and a decrease in referral volume for scoliosis evaluations.[22,23]

Notably, our study revealed a decline in the time dedicated to sports activities from the pre-COVID era to both the during-COVID and post-COVID periods. The reduction during the pandemic may be attributed to concerns about viral transmission and limited access due to lockdown measures. Surprisingly, this decrease persisted into the post-COVID period, suggesting potential long-term effects on social and health behaviors.

The results obtained in our study suggest that even in current days, where the most fearful period of the pandemic has passed, new strategies are needed to increase adherence to conservative treatment and engagement in sports activities in the post-pandemic phase. These may include the development of personalized adherence plans, integrating psychological support and behavioral interventions into routine care, and utilizing the power of telemedicine and mobile health applications to deliver remote support and education. Additionally, involving families in education and utilizing wearable devices to improve adherence could further enhance the effectiveness of these strategies.

In summary, our study, while acknowledging limitations such as reliance on patient-reported brace wear compliance, potential sample bias introduced by exclusively including individuals who attended in-person assessments during the pandemic, and a small sample size, underscores significant changes in the approach to conservative treatment and sports activities among adolescents with idiopathic scoliosis from pre-COVID to post-COVID periods. Expanding our observations to a larger patient population across different centers could help validate our results and provide further information.

Conclusions

In conclusion, our study highlights the changes in adherence to conservative treatment and engagement in sports activities for AIS patients during and after the peak period of the COVID-19 pandemic. The observed decrease, which persists even in the post-pandemic period, underscores important considerations for healthcare providers. This failure to return to pre-pandemic levels of compliance emphasizes the lasting impact of the pandemic on AIS management, necessitating innovative approaches to address these ongoing concerns.

List of abbreviations

AIS, Adolescent Idiopathic Scoliosis

NPC, Non Parametric Combination

Contributions

SM and LS, development of the study design, supervision; MCM and PC, data collection, data interpretation, writing, EB data analysis, writing, RC data analysis, AB, AC and RF data collection.

Ethics approval

All methods were carried out in accordance with the guidelines of the 2008 Helsinki Declaration. Ethical approval has been obtained on April 2023 (5627/AO/22).

Informed consent

All patients participating in this study signed a written informed consent form for participating in this study

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Conflict of interest

The authors declare no conflicts of interests.

Availability of data and materials

All data generated or analyzed during this study can be provided upon request.

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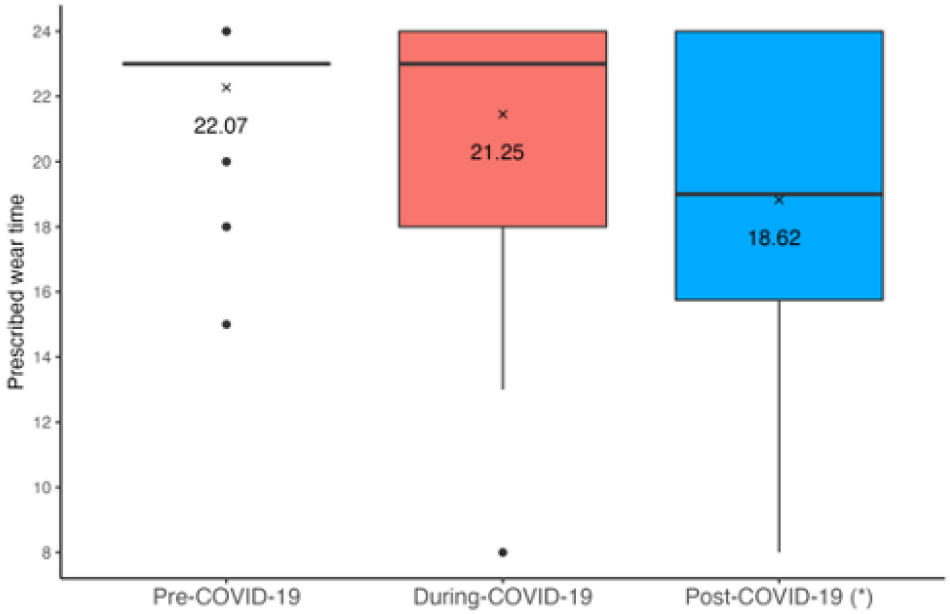

Figure 1. Variations in prescribed brace wearing time observed during the three periods considered (Pre-COVID-19 from January 2018 to December 2019, During COVID-19 from January 2020 to December 2021, Post-COVID-19 from January 2022 to December 2023). The asterisk indicates statistical significance in the comparison between the pre-COVID-19 and post-COVID-19 periods (p-value = 0.03).

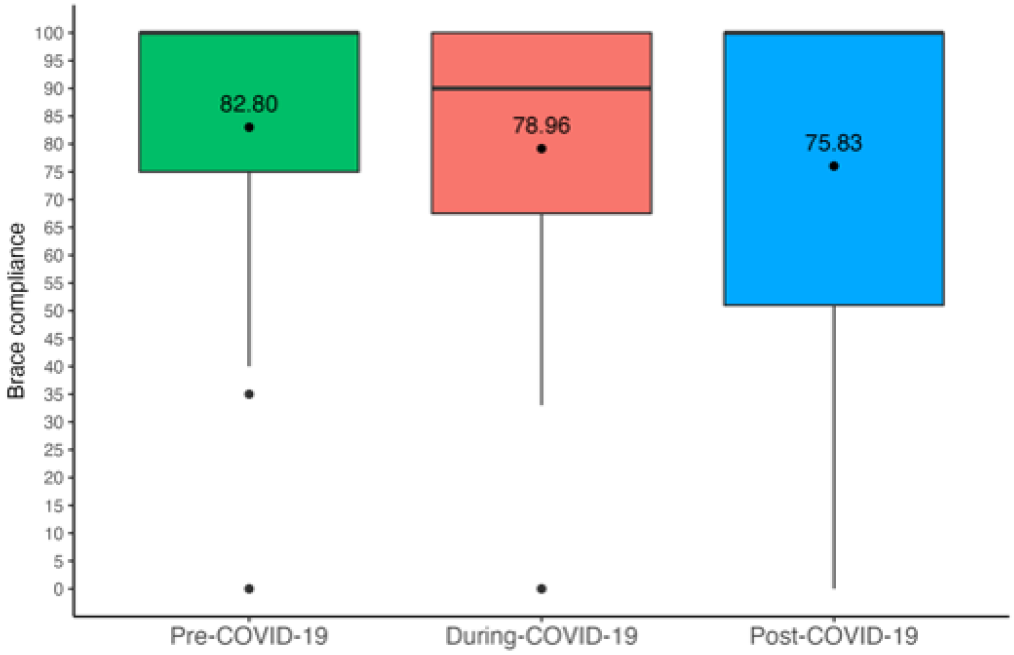

Figure 2. Variations in brace compliance observed during the three periods considered (Pre-COVID-19 from January 2018 to December 2019, During COVID-19 from January 2020 to December 2021, Post- COVID-19 from January 2022 to December 2023).

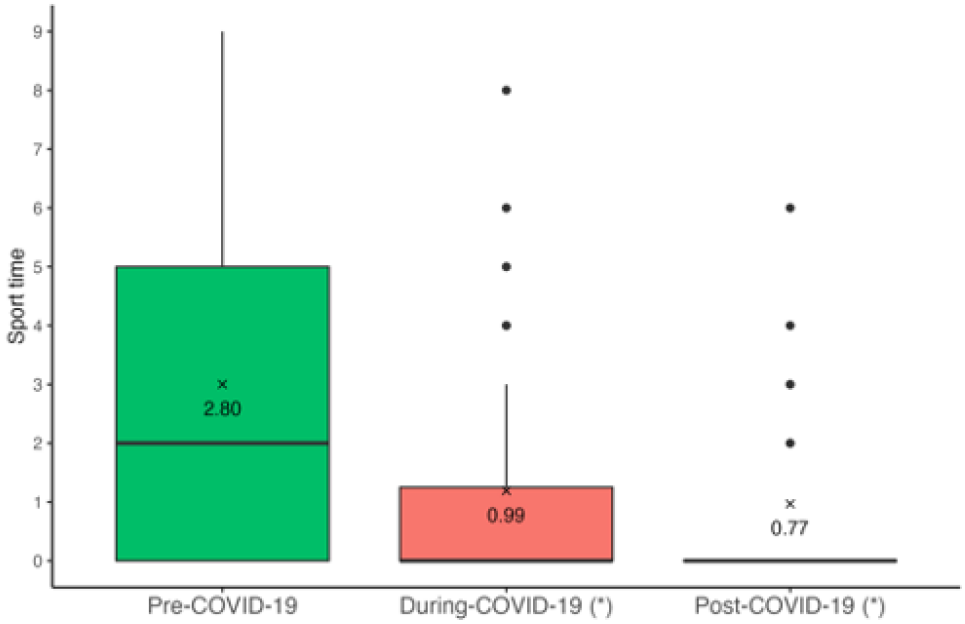

Figure 3. Variations in sports activity involvement observed during the three periods considered (Pre-COVID-19 from January 2018 to December 2019, During COVID-19 from January 2020 to December 2021, Post-COVID-19 from January 2022 to December 2023).

Asterisks indicate statistically significant differences when comparing the pre- vs. post- and pre vs. during COVID-19 periods (p-values 0.01, 0.04, respectively).

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