

# **Original Article**

# Risk factors associated with PTSD in a paediatric population exposed to the 14 July 2016, Nice terrorist attack: results from a 2-year longitudinal study

Morgane Gindt, Philippe Auby, Philippe Robert, Radia Zeghari, Nicolas Bodeau, Florence Askenazy\* and Arnaud Fernandez\*

# **Background**

The risk factors for post-traumatic stress disorder (PTSD) in children and adolescents following mass violence incidents, such as terrorist attacks, remain incompletely understood. In the aftermath of the 14 July 2016, terrorist attack in Nice, France, a dedicated paediatric consultation centre was established at the Children's University Hospital, the Nice Pediatric Psychotrauma Center (NPPC).

### Aims

This 2-year longitudinal study aims to identify and understand the influence of pre-trauma, trauma-related and post-trauma risk factors associated with the development of PTSD in children and adolescents following the 2016 terrorist attack in Nice.

### Method

Participants under 18 years of age at the time of the attack were recruited from the NPPC over 2 years, between 21 November 2017 and 22 November 2019. Assessments included semi-structured diagnostic interviews with children and/or parents, standardised clinical questionnaires for both parents and children and cognitive tests exclusively for children.

### Results

Two hundred and seventy-one children (mean age 8.10 years; 48.7% female) directly impacted by the terrorist attack, were assessed. Pre-traumatic factors (age, gender assigned at birth

and cognitive functioning) failed to predict PTSD. Two trauma-related factors, subjective fear intensity and lifetime number of traumatic events emerged as significant predictors. Concerning post-trauma factors, maternal symptoms (anxiety, depression and PTSD), child somatic symptoms and comorbid DSM-5 diagnoses played a crucial role in child PTSD. The final regression model demonstrated an 84% accuracy in predicting PTSD in children and adolescents ( $\chi^2[3] = 2.4$ , P < 0.001).

## Conclusions

These findings highlight the importance of assessing specific risk factors for PTSD in children and adolescents to deliver specialised and targeted care to young people and their parents following a terrorist attack.

### **Keywords**

Child and adolescent psychiatry; trauma and stress-related disorders; anxiety or fear-related disorders; observational study; evidence-based mental health.

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In Nice, France, thousands of children and their families were physically and psychologically affected by the 14 July 2016 (French National Day) terrorist attack. A truck crashed into a crowd of over 30 000 people, killing 86 people, including 15 children. This attack occurred in the context of a broader wave of terrorist attacks in public spaces across Europe in recent years. It is classified as an indiscriminate, retributive act of mass terrorism, i.e. targeting a large number of civilians opportunistically, lacking specific claims or strategy, but intended to inflict maximum harm and provoke widespread fear and terror. As such, it represents one of the most severe traumatic stress events, combining malicious intent, extreme violence, deliberate targeting against unprepared victims, collective stress and widespread media dissemination. The attack particularly affected entire families, including children and adolescents, and had a profound impact on individual and community resilience. <sup>1</sup>

Post-traumatic stress disorder (PTSD), a debilitating condition occurring after a traumatic event, includes symptoms of reliving, cognitive and mood alteration, avoidance and neurovegetative overactivation.<sup>2</sup> In the general paediatric population, approximately 15% of children exhibit PTSD.<sup>3</sup> In the wake of terrorist attacks, this percentage reaches 50–75%.<sup>4</sup> In the context of such an event, an

\*Joint last authors.

increasing volume of paediatric studies attempt to identify the risk factors that influence the development and maintenance of these disorders in youths.<sup>5</sup> To date, pre-trauma factors (age, gender assigned at birth, cognitive functioning), trauma-related factors (type of event, previous traumatic exposure, injury, subjective fear) and post-trauma factors (family and social support) have been identified to modulate PTSD development.<sup>5</sup>

# **Pre-trauma factors**

Pre-trauma factors studies about the impact of age after traumatic event exposure showed heterogeneous results in the youth population. For some authors, young children constitute the most vulnerable population, having less developed language, difficulties in regulating their emotions and in understanding the traumatic situation. Other studies underline that adolescents are more at risk than children, expressing risky behaviours, impulsivity and previous traumatic history. Previously, within the same cohort, we did not find any statistically significant effect of age for the development of PTSD. Gender assigned at birth has been suggested as a risk factor for developing PTSD, with girls having more extreme acute reactions to traumatic events than boys. Cognitive dysfunction, secondary to a traumatic event, has been

reported as a risk factor for developing PTSD.<sup>9</sup> In addition, the study by Breslau et al suggests that IQ modulates exposure to traumatic events, with children with an IQ above 115 having a reduced risk of exposure to such events.<sup>9</sup>

### **Trauma-related factors**

Concerning trauma-related factors, for children and adolescents, traumatic event types and characteristics modulate the rate of PTSD development. Interpersonal violence events seem to generate the highest rate of PTSD compared with catastrophes caused by natural disasters. <sup>10</sup> For example, in a recent meta-analysis, Dworkin et al found that the PTSD rate following sexual abuse is 41.5% 1 year after the event. 11 This rate in a paediatric population ranges from 50.6 to 75.2% after a terrorist attack.<sup>1,4</sup> During the traumatic experience, two main factors modulate PTSD development: the death of a loved one<sup>12</sup> and the lack of control.<sup>7</sup> Maalouf et al recently reported that, following the Beirut explosion, the percentage of PTSD in children and adolescents is higher among injured children, and those who suffered from material losses (e.g. home damage), especially those who had to be displaced following the explosion. 13 Previous traumatic exposure was also found to be a risk factor for PTSD in children and adolescents.<sup>14</sup>

### **Post-trauma factors**

Regarding post-trauma factors, somatic symptoms (such as abdominal pain, headache and pain in the limbs) are common complaints among the paediatric population after traumatic exposure. Children impacted by traumatic events exhibit such symptoms with a higher frequency and intensity than non-impacted ones. Lack of social support is recognised as the most crucial risk factor for PTSD. In children, social support is primarily related to family structure and parental DSM-5 diagnoses. Meta-analysis found that parental depression, anxiety and PTSD are the main predictors of long-term PTSD in children.

# **Aims**

This study examines the following two research questions: (a) what pre-trauma, trauma-related and post-trauma risk factors are associated with the development of PTSD in children and adolescents following the 14 July 2016, terrorist attack in Nice? and (b) how do these factors influence the development of PTSD in the affected population?

# Method

# Study design and setting

This cross-sectional longitudinal study was conducted in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines. All procedures involving participants complied with the ethical standards of the relevant institutional and national research committees and the Declaration of Helsinki (1975), as revised in 2013. Ethical approval was obtained from the French National Ethics Committee Northwest III (reference: 2017-A02212-51) and the study was registered with ClinicalTrials.gov (NCT03356028).

Participants and their families received detailed information about the study from a member of the research team prior to enrolment. Written informed consent was obtained from parents and young adults, and written assent from children and adolescents. Two study visits were conducted. At the first visit, participants underwent a clinical evaluation using a semi-structured diagnostic interview and a sociodemographic

questionnaire. An IQ test was performed at the second visit. All parents (including those of young adults) completed standardised questionnaires assessing anxiety, depression and PTSD. Assessments were conducted by clinicians at the Nice Pediatric Psychotrauma Center (NPPC, Southern France), specialised in the evaluation of traumatised children and adolescents. <sup>18</sup>

# **Participants**

A total of 271 children, adolescents and young adults were included in this study.

All participants were directly exposed to the terrorist attack and were under 18 years of age at the time of the event.

The recruitment period lasted 2 years, from 21 November 2017 to 22 December 2019.

Exclusion criteria included average intellectual disability (IQ below 50), deprivation of freedom after a judicial or administrative decision, exclusion period due to participation in another concomitant research study and being non-proficient in French for everyday communication and institutional interactions.

### **Variables**

Variables and measurements

Sociodemographic characteristics, including age at assessment, gender assigned at birth, details about the mass terrorist attack (level of subjective fear, injury during the attack), lifetime number of traumatic events, somatic symptoms (presence or absence of headaches, stomach aches, pains, heart palpitations, breathing difficulties and others) and use of care (first-aid and follow-up consultation) were collected.

PTSD and comorbidities were diagnosed according to DSM-5 criteria using two age-appropriate semi-structured diagnostic interviews: (a) for children aged 0–6 years: Diagnostic Infant and Preschool Assessment, <sup>19</sup> (b) for children and adolescents aged 7 to 18 years: the Schedule for Affective Disorders and Schizophrenia<sup>20</sup> (Kiddie-SADS).

Concerning the level of subjective fear, participants were asked about their subjective fear level using a Likert scale (from 0 = not at all, to 10 = extremely) and they were asked to indicate how scared they were during the 14 July 2016 attack.

The administered IQ tests were also age-appropriate:

- (a) Wechsler Preschool and Primary Intelligence Scale for children aged 3 to 6 years (WPPSI);<sup>21</sup>
- (b) Wechsler Intelligence Scale for Children (WISC)<sup>22</sup> for children and adolescents aged 6 to 16;
- (c) Wechsler Adult Intelligence Scale (WAIS)<sup>23</sup> for participants aged over 17.

All parents were asked to complete the validated French versions of the following questionnaires: PCL-5 (PTSD Checklist for DCM-5),<sup>24</sup> The State-Trait Anxiety Inventory (anxiety)<sup>25</sup> and Hamilton Depression Rating Scale (depression).<sup>26</sup> Mothers and fathers were divided into two groups depending on the presence or absence of symptoms according to the questionnaires cut-off scores.

Study participants were divided into two groups according to their scores on the PTSD section of the Kiddie-SADS: PTSD group versus no-PTSD group.

All assessments were carried out by, and in the presence of, clinicians specialised in assessing traumatised paediatric populations. To minimise potential biases from misunderstanding, participants were offered reformulations of the questionnaire questions and instructions.

Study size

No sample size was calculated as this is a longitudinal cohort study of a specific population: children and adolescents exposed to the Nice terrorist attack.

# Statistical analysis

Variables were divided into:

- (a) Continuous variables: age, IQ, subjective fear, lifetime number of traumatic events and number of comorbidities;
- (b) Categorical variables: gender assigned at birth, use of firstaid and follow-up consultations, presence of injury, date of inclusion, somatic symptoms, maternal symptoms and paternal symptoms.

All analyses were performed using R (version 4.0.2 for Windows; R Foundation for Statistical Computing, Vienna, Austria; https://cran.r-project.org/bin/windows/base/old/). All tests were bilateral and a *P*-value <0.05 was considered significant.

Descriptive statistics included mean, s.d., median, minimum and maximum for continuous variables. For categorical variables, percentages were used. The participant's assessment date was added to the variables analysed.

Student's *t*-test for continuous data and Fisher's exact tests were used to compare the PTSD group versus no PTSD group for pre-trauma (sociodemographic data: age and gender assigned at birth; and IQ test), trauma-related (level of subjective fear, presence of injury and use of first-aid and follow-up consultations) and post-trauma factors (comorbidities, somatic symptoms and parental symptoms).

Finally, a multivariate logistic regression model was performed based on the previous results. An automatic model selection was performed using an exhaustive search approach (package bestglm). Candidate predictor variables were those with P < 0.1 in the bivariate analysis. The best fit was evaluated using the information criterion AIC and BIC, and the resulting accuracy was evaluated by cross-validation.

Data considered missing at random were removed from the analysis (listwise deletion). This was not considered a problem since samples were still large enough after deletion.

# **Results**

# **Characteristics of participants**

A total of 271 children, adolescents and young adults aged 1 to 18 years (mean 8.10; s.d. = 4.1), see Figure 1 (in Supplementary

Table 1 Lifetime traumatic event according to age					
Traumatic event	0–6 years old N = 91, n (%)	7–12 years old N = 119, n (%)	13–18 years old N = 61, n (%)		
Motor vehicle accident	3 (3)	4 (3)	4 (7)		
Animal attack	3 (3)	3 (3)	1 (2)		
Natural disaster	0 (0)	1 (1)	0 (0)		
Medical trauma	4 (4)	9 (8)	4 (7)		
Physical abuse	0 (0)	3 (3)	2 (3)		
Sexual abuse	0 (0)	0 (0)	0 (0)		
Burns	1 (1)	1 (1)	1 (2)		
Drowning	1 (1)	2 (2)	0 (0)		
Witnessed	17 (19)	10 (8)	3 (5)		
Kidnapping	0 (0)	1 (1)	0 (0)		
Others	4 (4)	12 (10)	6 (10)		

materials available at https://doi.org/10.1192/bjp.2025.10378), who were exposed to the Nice terrorist attack participated in this study, with nearly equal numbers of girls (n = 132; 49%) and boys (n = 140; 51%). Twenty-five percent had experienced more than one traumatic event, with some reporting up to seven events (n = 69/271; 25.5%): medical trauma (n = 19/271; 7%), motor vehicle accident (n = 11/271; 4%), animal attack (n = 8/271; 3%), physical abuse (n = 6/271; 2%), burns (n = 4/271; 1.5%) and drowning (n = 4/271; 1.5%; see Table 1).

# **Group comparisons (PTSD/no PTSD)**

Almost two-thirds of participants were diagnosed with PTSD (167 of 271; i.e. 62%).

No significant differences were found between the PTSD and the no-PTSD groups regarding pre-traumatic factors, such as age, gender assigned at birth ratio and intellectual functioning, as reported in Tables 2 and 3. In contrast, the working memory index was modulated by PTSD (t(217) = 2, P < 0.05), lower in the PTSD group (mean 100.3, s.d. = 13.5) than in the no-PTSD group (mean 104.5, s.d. = 13.2).

For trauma-related factors, the PTSD group exhibited a higher intensity of subjective fear compared to the no-PTSD group (t(266) = 6.55, P < 0.001; mean 7.3, s.d. = 2.8). First-aid and follow-up consultations did not lead to significant differences.

Regarding post-traumatic factors, the PTSD group differed significantly from the no-PTSD group about the lifetime number of traumatic events (t(266) = -2.675, P < 0.01) and the number of comorbidities (t(226) = -11.34, P < 0.001). The lifetime number of traumatic events and the number of comorbidities were higher in

Group comparison between post-traumatic stress dis variables	order (PTSD) and no-PTSD group for continuous pre-traum	a, trauma and post-trauma
No PTSD group	PTCD group	

	No PTSD group		PI	TSD group		
Variables	n	Mean (s.d.)	n	Mean (s.d.)	t-test	<i>P</i> -value
Pre-trauma factors						
Age	105	8.6 (4.7)	166	9.2 (3.7)	-1.014	0.312
VCI	77	100.4 (13)	139	99.5 (14.2)	0.455	0.649
VSI	78	100.4 (12.2)	141	99.1 (11.8)	0.805	0.422
FRI	67	103.2 (14.8)	131	101.5 (13.4)	0.846	0.399
WMI	78	104.1 (13.6)	141	100.3 (13.5)	2	0.05
PSI	72	104.5 (13.2)	134	101.8 (12.2)	1.47	0.143
IQ	81	102.4 (13.2)	141	99.7 (13.2)	1.459	0.146
Trauma-related factors						
Subjective fear	105	5 (2.9)	166	7.3 (2.8)	-6.546	0.001
Post-trauma factors						
Cumulative trauma	105	1.2 (0.7)	165	1.4 (0.8)	-2.675	0.01
Comorbidities	105	0.8 (1.1)	166	3 (1.6)	-11.336	0.001

VCI, Verbal Comprehension Index; VSI, Visual Spatial Index; FRI, Fluid Reasoning Index; WMI, Working Memory Index; PSI, Processing Speed Index. The numbers in italics correspond to statistically significant results.

Table 3 Group comparison between post-traumatic stress disorder (PTSD) and no-PTSD group for categorical pre-trauma, trauma and post-trauma No PTSD group PTSD group Variables n (frequencies (%)) n (frequencies (%)) [95% CI] P-value Pre-trauma factors Gender assigned at birth Male 46 (45) 93 (56) [0.39-1.11] 0.119 Female 56 (55) 74 (44) Trauma-related factors First-aid 51 (50) 78 (47) [0.9-2.67]0.12 No Yes 50 (50) 89 (53) Follow-up 43 (43) 54 (32) [0.69-1.97] 0.634 No Yes 58 (57) 113 (68) Injury 96 (95) No 161 (96) [0.18 - 3.05]0.805 Yes 5 (5) 6 (4) Date of inclusion 2017 5 (5) 8 (5) 0.365 2018 68 (50) 68 (41) 2019 69 (31) 69 (41) 22 (14) 2020 22 (13) Post-trauma factors Somatic symptoms 35 (34) 18 (11) [2.19-8.68] 0.001 Yes 67 (66) 149 (89) Mother disorders 51 (55) 63 (40) 0.05 [1.04-3.15] No Yes 42 (45) 94 (6%) Father disorders 75 (88) 115 (81) [0.77-4.31] 0.21 No

10 (12)

Table 4 Logistic regression model					
Variables	Estimate	Standard error	z value	Pr(> Z )	
Maternal symptoms Subjective fear Comorbidities	1.1717 0.1933 1.2637	0.4640 0.0835 0.2064	2.525 2.315 6.121	0.0116* 0.0206* 9.28e-10***	
*P < 0.05; ***P < 0.001					

the PTSD group (m = 1.4, s.d. = 0.8; mean 3, s.d. = 1.6) than in the no-PTSD group (m = 1.2, s.d. = 0.7; mean 0.8, s.d. = 1.1 and mean 5, s.d. = 2.9).

The PTSD group was characterised by more somatic symptoms (89%) than the no-PTSD group (66%; odds ratio 4.3, 95% CI [2.19, 8.68], P<0.001). The date of inclusion in the study had no significant effect (see Table 3). We also evidenced that maternal symptoms were higher in the PTSD group (60%) than in the no-PTSD group (45%; odds ratio 1.8, 95% CI [1.04, 3.15], P<0.05) while this effect was not found for paternal symptoms.

# **Logistic regression model**

The algorithm identified the following variables as predictive factors of PTSD in children and adolescents: number of comorbidities and subjective fear intensity in children, and maternal symptoms. This model was statistically significant ( $\chi^2[3] = 2.4$ , P < 0.001) and the cross-validation estimate of accuracy was 0.836 (see Table 4).

The odds ratio to predict PTSD for the number of comorbidities, subjective fear intensity and maternal symptoms were, respectively, 3.54 (95% confidence interval, CI [2.4, 5.3]), 1.21 (95% CI [1, 1.4]) and 3.23 (95% CI [1.3, 8]).

Children exhibiting comorbidities were 3.5 times more likely to present PTSD than those with a single disorder (odds ratio 3.54).

This model suggests that the likelihood of PTSD in children is 3.2 times higher (odds ratio 3.23) in the presence of maternal symptoms.

27 (19)

Finally, children who experienced intense subjective fear during this traumatic event are 1.2 times more likely to develop PTSD (odds ratio 1.21).

# **Discussion**

This study addressed two key questions: what pre-, peri- and posttraumatic factors were associated with the onset of PTSD in children and adolescents exposed to the terrorist attack in Nice on 14 July 2016 and how these factors influenced the development of symptoms. Children and adolescents may develop other traumarelated disorders, such as attachment disorder, adjustment disorders or non-specific trauma-related disorders, as well as anxiety disorders or major depression with PTSD being the most common clinically recognised disorder after a traumatic event. In a previous study on the same cohort, we found that PTSD was the only disorder not influenced by age or development. We have also shown that in children and adolescents, PTSD is frequently accompanied by comorbid disorders such as anxiety disorders (in particular eparation anxiety disorder and generalised anxiety disorder) and impulse control disorders (intermittent explosive disorder or oppositional defiant disorder). Finally, attention deficit disorder with or without hyperactivity could also be associated with PTSD.

To advance understanding of PTSD in children and adolescents, this study aimed to identify risk factors associated with its development in youth exposed to a terrorist attack. While children and adolescents may also develop other trauma-related disorders, such as attachment disorders, adjustment disorders or non-specific trauma-related disorders as well as anxiety disorders or major

depression, PTSD remains the most recognised clinical outcome following a traumatic event. In a previous study based on the same cohort, we found that PTSD was the only disorder not influenced by age or development.<sup>1</sup>

Results indicated that in the PTSD group compared to the no-PTSD group, the following risk factors are statistically more important: first comorbidity and subjective fear, followed by somatic symptoms, lifetime number of traumatic events, maternal symptoms and working memory impairment. The regression model predicted 84% of the variance.

Pre-traumatic factors (age, gender assigned at birth and cognitive functioning) did not demonstrate a statistically significant effect. This finding is incongruent with previous studies using IQ reporting that young children, girls and global cognitive difficulties are known to be risk factors for developing PTSD after a mass trauma.<sup>6</sup>

However, these results are most often obtained in adult populations<sup>27</sup> or in the context of children affected by disasters triggered by natural hazards.<sup>6,28</sup> In addition, some authors postulate that pre-traumatic factors are predictive of PTSD below a certain threshold level of exposure.<sup>29</sup> This notion of threshold is argued in studies on September 11 and the Oklahoma City bombing. The development of PTSD in the case of terrorist attacks may affectdother persons indirectly, even in geographically remote areas, regardless of pre-traumatic factors.<sup>30</sup> In this study, all participants were present on the attack site and witnessed a horrific scene, fearing for their lives and the lives of their loved ones.<sup>1</sup> Some were confined for hours without information about what was happening outside. This represents a high level of exposure and therefore for all of them, this event constituted an experience of intense subjective fear.<sup>31</sup>

For gender assigned at birth, studies suggest that differences emerge after 12 years of age.<sup>32</sup> As the average age of our population is 9 years of age, no gender difference was reported.<sup>1</sup>

Among the trauma-related factors, subjective fear and the lifetime number of traumatic events were identified as predictors of PTSD in children and adolescents. These results are in line with the paediatric literature on PTSD.<sup>4</sup> In contrast, physical injuries during the attack did not generate a significant difference in the development of PTSD; several factors may modulate this result: first, the relatively small and heterogeneous sample size of physically injured children (n=11); second, all of them suffered from severe injuries and were in-patients, thus benefiting from intensive and appropriate psychological care during the acute and long-term phases.<sup>33</sup>

Finally, regarding post-traumatic factors, the key finding was that maternal symptoms, assessed through clinical questionnaires measuring depression, anxiety and PTSD, were significantly associated with the presence of PTSD in children and adolescents. This result is consistent with previous studies.<sup>34</sup> According to Chen et al, after the Wenchuan earthquake in China, parents may develop chronic PTSD (9.5%) or delayed PTSD (7.6%).34 The percentage of secondary trauma in parents is estimated to be around 15% in the case of paediatric injury in the USA.35 These symptoms impair parents' daily functioning and persist for a long time without management.<sup>36</sup> Most authors underline the fact that mothers' symptoms may modify behaviours, most particularly hypervigilance or avoidance, in parents, which are then learned or imitated by children.<sup>37</sup> For other authors, genetic or epigenetic leads are evoked as factors of vulnerability to PTSD.<sup>38</sup> However, little is known about the influence of maternal symptoms on children's PTSD course.

# **Limitations**

The first major limitation of the study is the lack of a control group. We chose to evaluate children directly impacted by this event and not a prior potential traumatic event. Indeed, the children of Nice

were all exposed to the attack of 14 July 2016, both by the media coverage of the event and by the changed atmosphere in the city during the months following the attack in a highly emblematic setting (Promenade des Anglais). Some authors have highlighted that in the context of terrorist attacks, notably September 11, indirect exposure via the media leads to PTSD symptoms in cities even far from New York.<sup>39</sup> Moreover, the 14 July 2016 attack was part of a series of terrorist attacks, including Charlie Hebdo (January 2015) and the Bataclan and the Terraces in Paris<sup>40</sup> (13 November 2015). The repetition of attacks increased the number of psychiatric disorders, including PTSD.<sup>40</sup>

The second major limitation of this study is the lack of assessment of parental symptoms prior to the event, which does not allow us to know whether parental symptoms are vulnerability factors or risk factors. Indeed, our study focuses only on current parental symptoms, with an assessment of anxiety, depression and post-traumatic stress symptoms; and does not retrospectively assess psychiatric history. It is, therefore, impossible to know whether the mothers developed symptoms before the event, concomitantly with the children, in the aftermath of the event or secondary to the children. A further limitation is the absence of parental cognitive assessments, which restricts our ability to investigate potential intergenerational cognitive vulnerabilities that may contribute to both parental and child PTSD. Future studies are needed to comprehend the influence of parental symptoms on child pathologies more fully. Such research could include clinical assessments and genetic and epigenetic markers.<sup>38</sup>

### **Clinical implications**

This longitudinal study examines the multiple factors impacting the development of PTSD in children and adolescents after a terrorist attack. Subjective fear, lifetime number of traumatic events and maternal symptoms emerge as significant predictors. These findings enable us to better detect children and adolescents at risk of developing PTSD after a terrorist attack, paving the way for more precise and personalised care in the future.

Morgane Gindt, PhD. Department of Child and Adolescent Psychiatry, Nice Pediatric Psychotrauma Center (NPPC), Nice University Children's Hospital (Lenval University Hospital), Nice, France; and CoBTeK (Cognition-Behaviour-Technology) Lab, Cote d'Azur University, Nice, France; Philippe Auby, MD, CoBTeK (Cognition-Behaviour-Technology) Lab, Cote d'Azur University, Nice, France; and CreApolis JL Noisiez Foundation, Biot Sophia-Antipolis, France; Philippe Robert, MD, PhD, CoBTeK (Cognition-Behaviour-Technology) Lab, Cote d'Azur University, Nice, France; and CreApolis JL Noisiez Foundation, Biot Sophia-Antipolis, France; Radia Zeghari, PhD, Department of Child and Adolescent Psychiatry, Nice Pediatric Psychotrauma Center (NPPC), Nice University Children's Hospital (Lenval University Hospital), Nice, France; and CoBTeK (Cognition-Behaviour-Technology) Lab. Cote d'Azur University, Nice, France: Nicolas Bodeau. Department of Child and Adolescent Psychiatry, Nice Pediatric Psychotrauma Center (NPPC), Nice University Children's Hospital (Lenval University Hospital), Nice, France; Florence Askenazy, MD. PhD. Department of Child and Adolescent Psychiatry, Nice Pediatric Psychotrauma Center (NPPC), Nice University Children's Hospital (Lenval University Hospital), Nice, France; CoBTeK (Cognition-Behaviour-Technology) Lab, Cote d'Azur University, Nice, France; and Regional Psychotrauma Centre (CRP) PACA-Corsica, Nice, France; Arnaud Fernandez (D), MD, PhD, Department of Child and Adolescent Psychiatry, Nice Pediatric Psychotrauma Center (NPPC), Nice University Children's Hospital (Lenval University Hospital), Nice, France; CoBTeK (Cognition-Behaviour-Technology) Lab, Cote d'Azur University, Nice, France; and Regional Psychotrauma Centre (CRP) PACA-Corsica, Nice, France

Correspondence: Arnaud Fernandez. Email: arnaud.fernandez@hpu.lenval.com

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# **Supplementary material**

The supplementary material is available online at https://doi.org/10.1192/bjp.2025.10378

# **Data availability**

The data that support the findings of this study are available from the corresponding author, A.F. on reasonable request

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### **Author contributions**

A.F. and F.A. contributed equally as co–senior authors. Concept and design: A.F., F.A. and M.G. Acquisition, analysis or interpretation of data: all authors. Drafting of the manuscript: A.F., F.A., P.R. and M.G. Critical review of the manuscript for important intellectual content: A.F., F.A., P.R. and M.G. Statistical analysis: N.B. and M.G. Administrative, technical or material support: A.F., M.G. and F.A. Supervision: A.F., F.A., P.A. and P.R.

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### **Declaration of interest**

None

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