



A Contribution to Validation of the Short Schema Mode Inventory in an Italian Clinical Versus Non-clinical Population

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Abstract

Schema therapy (ST) has been proven to be an effective psychotherapy model in the treatment of complex personality disorders. ST helps analyze causes of emotional, cognitive, and behavioral alteration in patients using schemas and modes (i.e., sets of emotional states, coping responses and schemas active in a given moment). ST finds its empirical validation in the short Schema Mode Inventory (SMI), a practical tool consisting of 14 subscales assessing 14 different mode categories, grouped in 4 (child, coping, parent and adult modes) high-order categories used to assess different modes at different times. We introduced the Italian validation of the short SMI to a sample of 707 participants, of whom 230 were psychiatric patients. Confirmatory factor analysis (CFA) provides evidence that the 14-dimensional model best describes the SMI's structure at a lower level. Higher-order CFA provides evidence for both four higher-level mode categories and one higher-level mode category, the four-mode category being the best approach. Internal reliability, test–retest stability and the relationship between the SMI's subscales have been evaluated with promising results. Clinical vs nonclinical subjects were compared with a multigroup CFA in order to test invariance and with a MANOVA and Bonferroni post hoc comparisons in order to test mean differences. A linear thread was found for all modes except Bully/Attack. While contributing to international research and to the diffusion of SMI and schema therapy, our results also suggest that SMI is a powerful tool for the assessment of modes in ST, both in therapeutic and diagnostic contexts.

Keywords Schema therapy · Schema Mode Inventory · Schema modes · Personality disorders · Differential susceptibility

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Introduction

Schema therapy (ST) has been shown to be a new organized and systematic psychotherapy, which incorporates aspects of cognitive behavioral therapy, psychoanalysis, Gestalt therapy and emotionally focused therapy (Young 1990). ST has become a very promising therapy system in the last two decades, and it has been implemented in many clinical and forensic settings. ST is based onto two main constructs: early maladaptive schemas (EMSs) and modes.

In schema therapy (Young 1990; Young et al. 2003), EMSs are defined as “a broad, pervasive theme or pattern, comprised of memories, emotions, cognitions, and bodily sensations, regarding oneself and one’s relationships with others, developed during childhood or adolescence, elaborated throughout one’s lifetime and dysfunctional to a significant degree” (Young et al. 2003 p. 7; Thimm 2010). EMSs arise from the frustration of psychological core needs in childhood (e.g., secure attachment, expression of valid needs, realistic limits) through ongoing patterns of adverse experiences with family members or peers, traumatization, or inappropriate boundaries (Martin and Young 2010). EMSs perpetuate themselves through cognitive distortions, self-defeating life patterns, and maladaptive coping styles while leading directly or indirectly to psychological distress and to personality disorders (Young 1990; Young et al. 2003). Schemas are a major determinant of how individuals think, feel, behave, and interact socially (Martin and Young 2010).

EMSs are usually described as personality traits (Young 1990; Young et al. 2003) that operate on the deepest level of cognition, usually outside of awareness and make the individual psychologically vulnerable to the development of psychopathology (Hedley et al. 2001; Jovev and Jackson 2004; Reeves and Taylor 2007; Waller et al. 2007). Modes are usually described as a dysfunctional cognitive-emotive state and can be defined as a combination of schemas, coping responses, and the emotional state activated in a given person at a specific time (Lobbestael and Arntz 2010; Young et al. 2007).

Modes are both the core aspect and the most complex part of ST (Lobbestael et al. 2008; Young et al. 2007). Initially, the mode model was thought to be an efficient way of describing emotional, cognitive, and behavioral shifts displayed by patients suffering from severe personality disorders (PDs) (Lobbestael et al. 2007). This makes it a precious tool for assessing and treating PDs. Modes can be divided into four categories in the ST model: child modes, dysfunctional parent modes, dysfunctional coping modes and healthy modes.

The child modes are characterized by strong distressing emotions such as an intense fear of being abandoned, anger, and strong sadness. The basis for the development of these modes is a lack of recognition regarding basic emotional needs; the patients’ needs were never satisfied during their childhood. In this category of modes, there is also a functional mode developed when the patients’ primary emotional needs are fulfilled. There are five child modes. The Enraged Child (EC) is characterized by heightened and excessive feelings of aggression, expressed through the damage of people and property (“I physically attack people

when I am angry at them”). The Impulsive Child (IC) is characterized by impulsive and direct self-gratification that cannot be delayed (“It is impossible for me to control my impulses”). The Angry Child (AC) presents feelings of anger and frustration that are related to a history of unmet needs (“I am angry with someone for leaving me alone or abandoning me”). The Undisciplined Child (UC) is characterized by a lack of efforts made to fulfill boring tasks. The patient easily gives up as a result; this leads to strong feelings of frustration (“If I can’t reach a goal, I become easily frustrated and give up”). The patient feels fear, sadness, loneliness and worthlessness in the Vulnerable Child (VC) mode (“I often feel alone in the world”). However, the Happy Child (HC) is characterized by feelings of love, safety, acceptance and spontaneity (“I feel loved and accepted”).

The second category concerns dysfunctional coping modes, based on an excessive use of strategies of overcompensation, avoidance and surrender. We find the Detached Protector (DetP) with the avoidance strategy. This mode is based on the emotional and psychological withdrawal of the individual, the suppression of feelings, depersonalization and a lack of human perceived contact. Feelings of emptiness, abulia, and boredom are typical markers (“I don’t want to get involved with people”). The Detached Self-soother (DSS), on the other hand, is characterized by emotional detachment based on compulsion and on the actuation of distracting and soothing tasks: TV watching, eating, promiscuous sex, and drug abuse (“In order to be bothered less by my annoying thoughts or feelings, I make sure that I’m always busy”). We find overcompensation modes on the other side of the spectrum, opposed to the avoidance modes. According to Lobbestael et al. (Lobbestael et al. 2010), two subscales can be found: the Self-Aggrandizer (SA), characterized by egoistical behavior, lack of empathy, and lack of respect for shared rules (“I do what I want to do, regardless of other people’s needs and feelings”), and the Bully/Attack (BA), characterized by the will to systematically harm others through physical, verbal, and psychological attacks. These attacks are also related to antisocial or criminal actions (“I mock or bully other people”). The final dysfunctional coping mode is Compliant Surrender (CS): the passive and submissive behavior that stems from the patient needing everyone’s approval. Instead of risking conflict or refusal, the individual tolerates abuse in spite of his/her needs or desires (“I allow other people to criticize me or put me down”).

The third category of modes contains the dysfunctional parent modes; these modes stem from excessively critic and strict parental behavior that the patients internalized during childhood, thus imposing excessively high standards on themselves in adult life. We find the Punitive Parent (PP) and the Demanding Parent (DP) in this category of modes. The first subscale refers to an interiorized voice coming from punitive attachment figures. This mode is characterized by self-directed anger, related to a desire for punishment for having needs (“I do not allow myself to do pleasurable things that other people do because I am bad”). However, those needs are normal. People feel a strong pressure to reach excessively high standards and goals in the DP mode. They need to be perfect if they want to be accepted by others. The needs of others almost always trump their own needs (“I am hard on myself”).

The last mode is the Healthy Adult (HA); it shows significant adaptive functions and a strong mediation between different elements. It protects the VC and sets

boundaries on behaviors to the AC and the IC; it fosters and supports the HC, giving it functionality. It replaces maladaptive coping strategies and, finally, stops the dysfunctional parents. This mode also functions as an adult: it lets the patient work, take responsibilities, be a caregiver, etc. while also engaging in pleasant and stimulating activities such as sex, sports, and cultural and aesthetic interests (“I am capable of taking care of myself.”).

The aim of ST is the development and consolidation of the HA mode so that patients can learn to identify and modify dysfunctional modes (Young et al. 2003). More recent developments of ST incorporate the Happy Child mode with the Healthy Adult mode, creating integrative adaptive modes (Simeone-DiFrancesco et al. 2015; Young et al. 2007).

ST has been influenced by specificity hypothesis in the past decades, according to which different types of dysfunctional schemas and cognitive distortions could help differentiate psychopathologies (Leung and Poon 2001). In line with this, the schema therapy literature has shown that different modes are pathognomonic of different disorders (Lobbestael et al. 2010). Moreover, this distinction may be very useful both during ongoing therapy with different patients (e.g., in patients such as “attention seeker” and “over controller” (Van Vreeswijk et al. 2015, p. 452) emerging during individual therapy, it is very useful to identify and name these modes) and for the conceptual framework proposed by different waves of ST. Different authors put together functional modes, adding new functional copying modes such as cooperation and self-efficacy (Simeone-DiFrancesco et al. 2015). In this respect, different opinions can be found on the number of modes in the theoretical framework. Some studies have proposed increasing the number of modes (Lobbestael et al. 2007), claiming that including more modes can be useful to create a link between the patients’ internal mental state and their behavior; this would be especially useful during an episode of emotional dysregulation. However, other authors claim that there is no need to increase the number of modes. In fact, for some applications of ST (e.g., couple schema therapy), some authors claim that a simplification of the model is necessary (Dadomo et al. 2018; Simeone-DiFrancesco et al. 2015). To understand a patient who shows severe emotional dysregulation, using the concept of modes is essential. The mode theory’s basic concept shows that different mental states have different purposes and are related to different basic needs (Dadomo et al. 2018). In addition, if the therapy itself works directly with one active mode at a given moment, it follows that it is very important to be able to identify it precisely.

In empirical research on the effectiveness of ST compared to transference-focused psychotherapy (TFP) regarding borderline personality disorder (BPD), ST has been demonstrated as more effective than TFP; this has been indicated by cost effectiveness, quality of life, and drop-out rates (Giesen-Bloo et al. 2006; Van Asselt et al. 2008). When applied in group formats and in general healthcare, ST showed similar results (Farrell et al. 2009; Nadort et al. 2009). Regarding group schema therapy, similar results were found in the treatment of BPD (Farrell et al. 2009). Three pilot studies on inpatients also showed high effectiveness (Reiss et al. 2013). Furthermore, a recent study by Bamelis et al. (2014) found ST to be more effective than treatment as usual and clarification-oriented therapy. This information was gathered through the use of interview-based measures

among patients with Cluster C, paranoid, histrionic, and narcissistic personality disorder (PD). Studies on other patient populations, such as forensic patients, patients with cluster C PD and patients with cluster B PD, also confirmed the efficacy of ST on these patient populations (Bernstein et al. 2007). Other studies are shifting their focus to how ST can be used to treat depression (Renner et al. 2017), on what makes it such an efficient multidagnosis therapeutic model (Lemmens et al. 2016), and on exploring different perspectives of ST from the patient and the therapist's point of view (de Klerk et al. 2017).

While clinical and theoretical interest in ST has grown in the last decade, only a few empirical tests have been conducted on the validity of the mode model. The development and validation of the short Schema Mode Inventory (SMI) is one of the efforts of empirical validation of the mode model. The SMI is a tool that the therapist uses to evaluate precisely which mode is active at a given time. It was developed and validated by Lobbestael et al. (2010), and it includes 14 subscales divided in the 4 categories described above. The long version of the SMI is no longer available on the site <http://www.schematherapy.com/id49.htm> and was never published or validated.

The SMI is extremely useful for mode identification. This makes the SMI a precious therapeutic tool because third-wave therapy is almost exclusively based on mode treatment, unlike the schema-oriented first wave. The Young Schema Questionnaire (Schmidt et al. 1995) gauges precocious maladaptive schemas, which are trait, not state, characteristics (i.e., modes). The YSQ gathers limited information because schemas are identified easily by an expert clinician. The SMI, however, allows for a reliable measure of modes, which are harder to identify when starting treatment, regardless of the clinician's expertise. This is caused by their tendency to change quickly, particularly in cases of severe psychopathology. The YSQ items therefore are centered on the subject's beliefs (e.g., an item of the "inadequacy scheme" says, "I do not deserve love, attention and respect from others"). The SMI items instead tend to focus on subjects' experiences and feelings (e.g., an item of the "vulnerable child" mode says: "I feel profoundly inadequate, imperfect and lacking.").

The present research is a contribution to the development of the short Schema Mode Inventory's Italian version. All studies to date have considered only patients diagnosed with a clear axis I or axis II diagnosis (according to DSM-IV-TR, American Psychiatric Association 2000) and have never specified whether this diagnosis is exclusive or predominant. Clinical experience usually shows that is difficult to have an Axis II diagnosis without an Axis I diagnosis. For this reason, we decided to study patients with Axis I in comorbidity with Axis II and patients who had an exclusive Axis I or Axis II diagnosis.

- Our first goal was to verify which of the 14-, 8-, and 4-factor models (Lobbestael et al. 2010) better represented our data.
- We then wanted to verify if the second-order subdivision into 4 factors, originally proposed by Young et al. (2003), is the best model when compared to the recent proposition of grouping modes differently from those Young origi-

nally proposed (i.e., incorporating HC and HA in a single functional mode; cp. Simeone-DiFrancesco et al. 2015).

- The third objective was to test a solution to a single superordinate factor.
- The fourth objective was to verify the hypothesis that dysfunctional modes present a monotonic increase from the controls, to Axis I patients, to Axis II patients and to mixed patients, while the functional modes decrease in the same direction.
- Ultimately, we verified the reliability of the SMI.

Method

Sample

The current study included a total of 709 subjects. Preliminary analysis (examining the accuracy of data) excluded two cases due to missing values: 22 items were omitted in the first case, and 11 items were omitted in the second case. Missing values (<10%) were computed using the mean of the items: 36 items out of 118 (31%) present missing values, and only 9 out of 36 have more than one missing: item 69 (9 missing); item 23 (7 missing); items 19 and 112 (4 missing); items 37 and 41 (3 missing);, and items 27 and 28 (2 missing). Due to the small amount of missing values, we replaced missing data with the item mean instead of excluding the subject and losing fundamental information, although we are conscious that this approach diminishes the natural variability that might have been found had results not been missing. Data were extracted and analyzed from 707 participants, including 477 nonpatients and 230 psychiatric patients. To simplify a comparison with previous studies that were performed before the DSM-5 (American Psychiatric Association 2013) was available, we used the DSM-IV-TR (American Psychiatric Association 2000) categorization of psychopathology of Axis I (general psychopathology) and Axis II (personality disorders). Specifically, the clinical group included 67 patients with Axis I disorder, 93 patients with Axis II diagnoses and 70 patients with both Axis I and Axis II diagnoses. The sample comprised 305 males (43.3%) and 400 females (56.7%) with a mean age of 36.50 years ($SD=12.09$, range 18–89). There was no significant difference of gender between nonpatients and patients. For the participants' educational level, 16.9% completed primary school, 39.2% completed secondary education, and 5.7% completed low-level vocational studies, while 18.9% obtained a first degree, 17.2% obtained a higher degree, and 1.5% achieved a doctorate. Nonpatients had a significantly higher educational level than patients. Moreover, 55.5% of the participants were single, 37.1% were married or lived together, 6.5% were separated or divorced and 0.9% were widowers. Data from the clinical sample were collected among inpatients of the private hospital "Villa Maria Luigia" in Monticelli Terme (PR) and of the "Raymond Gledhill" community for drug addicts in the province of Rome and among outpatients of private psychotherapists trained in ST. The diagnosis was given by the psychotherapist who currently was treating the patient; the patient granted access to his/her diagnosis in the informed consent. Control group members were contacted depending on their geographic proximity to those of the study group.

Table 1 Description of the psychiatric patients with Axis I diagnoses (*N* = 67), Axis II diagnoses (*N* = 93) and Axis I-II diagnoses (*N* = 70)

	Axis I patients <i>N</i> (%)		Axis I-II patients <i>N</i> (%)		Total <i>N</i> (%)			
	Axis I patients <i>N</i> (%)	Not otherwise specified	Axis I-II patients <i>N</i> (%)		Substance abuse	Eating disorder	Major depressive disorder	Mood disorder
Substance abuse	17 (25.4)	9 (9.7)						
Eating disorder	4 (6.0)	Borderline PD	16 (17.2)	Borderline PD	31 (44.4)	7 (10.0)	4 (5.7)	1 (1.4)
Major depressive disorder	8 (11.9)	Narcissistic PD	17 (18.3)	Narcissistic PD	2 (2.9)	1 (1.4)	1 (1.4)	1 (1.4)
Anxiety disorder	15 (22.4)	Dependent PD	12 (12.9)	Dependent PD	1 (1.4)	0 (0.0)	1 (1.4)	1 (1.4)
Mood disorder	2 (3.0)	Avoidant PD	4 (4.3)	Avoidant PD	2 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)
Sexual dysfunction	9 (13.4)	Obsessive-compulsive PD	3 (3.2)	Obsessive-compulsive PD	2 (2.9)	0 (0.0)	3 (4.3)	0 (0.0)
Adjustment disorder	8 (11.9)	Antisocial PD	3 (3.2)	Antisocial PD	3 (4.3)	0 (0.0)	1 (1.4)	0 (0.0)
Dythymic disorder	1 (1.5)	Histrionic PD	17 (18.3)	Histrionic PD	3 (4.3)	0 (0.0)	2 (2.9)	0 (0.0)
Somatiform disorder	3 (4.5)	Schizotypal PD	3 (3.2)	Schizotypal PD	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.4)
		Paranoid PD	5 (5.4)	Paranoid PD	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
		Schizoid PD	4 (4.3)					
Total	67 (100)		93 (100)		45 (64.5)	8 (11.4)	13 (18.5)	4 (5.6)
								70 (100)

Patients with various diagnoses were recruited to achieve high variability (see Table 1).

Test–retest reliability was assessed in 50 subjects from the normal population. This subsample consisted of 25 females and 25 males with a mean age of 32 years (range 18–57 years). Of these, 4% attended only primary school, 62% completed secondary education, 28% obtained a first degree and 6% obtained a higher degree.

Procedures

All participants were informed about the purpose of the study and received written informed consent. No legally authorized representatives were assigned because all patients were deemed able to provide informed consent. They were tested individually. Patients completed the paper-and-pencil questionnaires and researchers/recruiters signed copies with an alphanumeric code to ensure anonymity. All patients were initially evaluated by a psychiatrist or psychologist in order to assess if they met one or more diagnostic criteria of the DMS IV-TR (American Psychiatric Association 2000).

Participants were excluded from this study if they were under 18 and over 90, had an < 80 IQ, had insufficient knowledge of Italian, were intoxicated during testing, or had an established diagnosis of schizophrenia or dementia. The administration time of this short SMI was approximately 30 min. The protocol of this study was approved by the internal ethics committee of the Department of Human, Social and Health Science, University of Cassino and Southern Lazio (Italy) and of the Psychology School of Padua (number 2464).

Instruments

Short Schema Mode Inventory (SMI; Lobbestael et al. 2010). English items were translated into Italian by bilingual professionally certified ST therapists of the Istituto di Scienze Cognitive (Cognitive Sciences Institute). The SMI measures the presence of 14 schema modes. It consists of 118 items with 4–10 items per scale, scored on a 6-point Likert scale (from “Never or almost never” to “All of the time”). Different studies have been performed to confirm the validity of the SMI’s psychometric properties.

The first study on the construction, reliability and validity of the short SMI version was conducted in 2010 (Lobbestael et al. 2010) through a series of confirmatory factor analysis (CFA). This validation, performed on 863 participants, including 319 nonpatient controls, 136 patients with Axis I and 236 patients with Axis II disorders, has confirmed the 14-factor model’s superiority over the 8 and 4 models. A good construct validity and a satisfactory internal consistency (Cronbach’s alpha ranging from the .79 to .96) were also found in the short SMI version; finally, a good test–retest reliability has been demonstrated over a period of 30 days. A significant linear trend was found for all subscales, indicating that the scores of all dysfunctional modes increased monotonically over the three groups (controls, Axis I patients, Axis II patients), while the scores of the two functional modes decreased

monotonically over the three groups. The results emerging from this pioneering research confirmed that the short SMI is a test with good psychometric properties.

Two other studies conducted by Reiss et al. (2012, 2015) replicated the psychometric surveys used in the Dutch study to validate a German and a Danish version of the short SMI. Consistent with the findings from the study of Lobbestael et al. (2010), the 14-factor model was confirmed over the 8 and the 4 models, and the internal reliability showed adequate results, as well as intercorrelation between the subscales. Known-group validity was always significant except for the subscale “Self-Aggrandizer” in the German study, with psychiatric patients showing highly significant scores than the control group.

The available studies on the Dutch, German, and Danish versions of the SMI support its use in therapeutic settings as a reliable and valid assessment instrument for working with modes in ST. For the Netherlands, the mode model is seen as clinically useful and effective, and it is frequently employed in psychotherapy practice in Germany and Denmark. Therefore, an assessment instrument for ST modes such as the SMI is known as a very functional instrument for Italian therapists.

For this reason, a total of 109 Axis II patients and 241 controls were involved in the initial validation of SMI in the Italian population in a previous study (Panzari et al. 2016). This study confirmed a goodness of fit for the 14-factor structure; therefore, it is a significant and adequate model, with a fit that represents the nature of the Italian version of the SMI. The correlations between items, intercorrelations between subscales and discrimination between clinical and nonclinical participants almost matched those of the previous studies. The limits to this study were the limited numbers of participants, the fact that it only focused on Axis II personality disorders, and the absence of test–retest analysis.

Statistical Analysis

Most statistical analyses were performed using the statistical program SPSS version 21, while CFA was carried out with LISREL 8.80 (Jöreskog & Sörbom 2006).

To assess the factorial structure of the SMI, the construct validity was assessed by a first-order CFA on all 118 test items and by a second-order CFA on 4 different factors and on a single factor. For the first-order CFA, we analyzed the goodness-of-fit indexes of three different models: most differentiated model (14 factors), semi-parsimonious model (8 factors), and parsimonious model (4 factors). A multigroup confirmatory factor analysis using maximum likelihood estimation was conducted to evaluate the measurement invariance of the 14-factor model (the best model in previous CFA analysis) across clinical and nonclinical participants. For the second-order CFA, we analyzed the goodness-of-fit indexes of three different models: the classic 4-factor model with HA alone, 4 factors that grouped HA and HC together, and 1 general factor of psychopathology. The graphic representations of the different models can be found in Figures 1–6s.

To assess the adequacy of the model, we used 5 fit measures as follows: the χ^2 to degrees of freedom ratio, comparative fit index (CFI), non-normed fit index (NNFI), standardized root mean square residual (SRMR), and root mean square

error of approximation (RMSEA). The χ^2 statistic may be used as a measure of fit between the sample covariance and fitted covariance matrices (Byrne 2005). Values of the χ^2 to degrees of freedom lower than 2 or 3 seem to indicate a reasonable fit. The CFI and NNFI range from 0 to 1, with higher values indicating a better fit. A CFI or NNFI greater than 0.95 indicates a good fit. The SRMR ranges from 0 to 1, with lower values indicating a better fit. SRMR values $\leq .08$ indicate a good fit. The RMSEA is another fit index that considers the error of approximation in the population (Byrne 2005). RMSEA values $< .05$ indicate a good model fit, and RMSEA values between $.06$ and $.08$ indicate an acceptable model fit. Above $.08$ indicates a good model fit (Schreiber et al. 2006). In order to compare different models, we used Bayes information criterion (BIC), with lower values indicating better fit (Schreiber et al. 2006). To assess the model fit of nested models, the Δ CFI criterion was adopted (Cheung and Rensvold 2002). As recommended by Cheung and Rensvold (2002), if the difference in the CFIs between two nested models (Δ CFI) is smaller than $.01$, the hypothesis of no difference in fit between the two competing models should not be rejected. We decided to use the Δ CFI instead of the χ^2 difference test because it is less sensitive to sample size. Significant results for the χ^2 difference test indicate that the model with smaller χ^2 has a statistically better fit. This test, however, with large samples tends to yield a significant test result for very trivial differences.

We examined skewness and kurtosis of all variables according to Kim's guideline (Kim 2013). For sample sizes greater than 300, an absolute skewness value larger than 2 or an absolute kurtosis larger than 7 may be used as reference values for determining substantial non-normality. Only one variable exceeds the cutoff for skewness ("Enraged Child", skew = 2.117), and no variables exceed the cutoff for Kurtosis; these results therefore support the use of parametric tests. All factor intercorrelations between the Italian SMI subscales were evaluated with Pearson's correlation. Internal consistency was tested by calculating the Cronbach's α value for each of the 14 subscales. This coefficient varies between 0 and 1, with values close to 1 implying good homogeneity of the items (α values $> .70$ indicate good internal reliability). Pearson's correlation coefficients, the intraclass correlation coefficient (ICC), and a paired t test were conducted to assess test-retest reliability. The results were interpreted by Bonferroni's correction for multiple testing ($p = 0.05/14 = .004$). Baseline and follow-up measures were assessed over a 30-day period (with 3 days of tolerance).

Known-group validity was evaluated by performing MANOVA (Multivariate ANalysis Of VAriance) between scores on the subscales of the SMI (dependent variables) and the different analyzed samples (independent variables). Additionally, orthogonal polynomial contrasts were used to evaluate a monotonic increase from nonpatient control groups, in patients with an Axis I diagnosis, in patients with an Axis II diagnosis, and in patients with a combined (Axis I and Axis II) diagnosis. Additional analyses were conducted to examine group differences (control group versus clinical group) as a test of discriminant validity for each of the subscales. Effect sizes as measured by Cohen's d were also reported, with $.20$, $.50$ and $.80$ representing small, average and large effects, respectively (Cohen 1992).

Results

Factor Structure of the SMI

Confirmatory factor analysis was used to assess the fit of the previously described models of the SMI items. The results presented the most differentiated model (14 factors) as significantly better than the more parsimonious ones consisting of 8 or 4 factors (see Table 2). The χ^2 to degrees of freedom ratio indicated that the model of 14 factors has a better fit than the other analyzed models, as shown by the lowest BIC. Furthermore, the CFI and NNFI signaled a good fit of the model. Finally, RMSEA had an acceptable value. This finding was successfully confirmed by previous researchers (Lobbestael et al. 2010; Reiss et al. 2012; Reiss et al. 2015). The results confirmed both configural invariance of the 14-factor model across clinical and nonclinical participants ($\chi^2=30633.164$ (13388, $n=654$), $p<.001$; NNFI=.919; CFI=.922; RMSEA=.060) and the equality of factor loadings and factor correlations across groups ($\chi^2=32419.233$ (13597, $n=654$), $p<.001$; NNFI=.917; CFI=.919; RMSEA=.063; Δ CFI=.003), showing an adequate fit (Cheung and Rensvold 2002).

Table 1s shows the factorial solutions obtained for each scale; each item is adequately saturated ($>.35$) with its own reference factor, with the exception of five items. Figures 1–3s show the graphic representation of each solution.

Second-order analysis showed good fit indexes both for the classic solution with four second-order factors (Child modes: VC, AC, EC, IC, UC, and HC; Coping modes: CS, DetP, DSS, SA, and BA; Parent modes: PP and DP; and Healthy modes: HA) and for the solution with one single second-order factor, the BIC being lower for the four second-order factors model and thus indicating a better fit for this solution (see Table 2). The alternative four second-order factors model that incorporated HC and HA into the same factor related to integrative adaptive modes did not converge, since a parameter could not be identified. Figures 4–6s show the graphic representation of each solution.

Table 2 Goodness-of-fit indices of the SMI (118 items) ($N=707$)

Model	CFI	NNFI	SRMR	RMSEA	χ^2	<i>df</i>	$\chi^2/(df)$	BIC
14 factors	.957	.956	.069	.057	21760,288	6694	3.251	23905.745
8 factors	.947	.946	.077	.068	29031,722	6757	4.297	30763.834
4 factors	.934	.933	.080	.090	45384,346	6779	6.695	46972.115
14 first order factors + Young's 4s order factors	.951	.950	.082	.062	25256,783	6766	3.733	26929.846
14 factors + 1s order factor	.951	.950	.083	.063	25423,516	6771	3.755	27063.774

CFI comparative fit index, NNFI non-normed fit index, SRMR standardized root mean square residual, RMSEA root mean square error if approximation, χ^2 Chi square, *df* degrees of freedom

Internal Consistency

Mean Cronbach's alpha for the Italian version of the SMI was .80, ranging from $\alpha = .66$ to $\alpha = .93$ (see Table 3). For the higher-order factors, Cronbach's alpha was .88, .74 and .67 for Child, Coping and Parent Modes, respectively. Adult encompasses only one item, and it was not possible to compute an alpha. This result indicates an adequate level of internal consistency among the items of the instrument. The mean item loadings of each subscale were also acceptable, with a global item loading mean of .62. Similar results were obtained in previous research (Lobbestael et al. 2010; Reiss et al. 2012, 2015), with lower results for the same item.

The mean inter-item correlations varied from .19 to .59 and had a low mean of .32. These data are lower than those emerging in the previous validations (Dutch = .47; German = .44; Danish = .47). The lowest Cronbach's alpha values and inter-item correlation were found for the same mode (the Bully/Attack).

Factor Intercorrelations

Table 4 describes the factor intercorrelations between the Italian SMI subscales. The results showed a significant positive correlation in the maladaptive modes and in the adaptive modes. Moreover, the adaptive factors significantly correlate negatively and statistically with the dysfunctional factors. The mean intercorrelation of the two functional factors (HA and HC) was .66; the mean correlation between the maladaptive mode concerning the Child (VC, AC, EC, IC and UC) was .58, that

Table 3 Internal reliability SMI ($N = 707$)

SMI subscales	Number of item	Mean inter-item correlation	Cronbach's α	Mean item loading
Vulnerable child	10	.59	.93	.77
Angry child	10	.34	.84	.60
Enraged child	9	.43	.86	.67
Impulsive child	8	.42	.85	.69
Undisciplined child	5	.39	.76	.61
Happy child	10	.42	.87	.68
Compliant surrender	7	.25	.70	.58
Detached protector	9	.41	.85	.65
Detaches self-soother	4	.42	.75	.68
Self-aggrandizer	10	.25	.77	.48
Bully/attack	9	.19	.66	.48
Punitive parent	10	.38	.85	.67
Demanding parent	7	.33	.77	.60
Healthy adult	10	.27	.79	.55
Mean	8.4	.36	.80	.62

Table 4 Factor inter-correlation between the short SMI subscales (N = 707)

	VC	AC	EC	IC	UC	HC	CS	DetP	DSS	SA	BA	PP	DP
AC	.70**												
EC	.50**	.68**											
IC	.52**	.66**	.72**										
UC	.61**	.54**	.42**	.50**									
HC	-.71**	-.45**	-.34**	-.32**	-.46**								
CS	.54**	.45**	.28**	.38**	.43**	-.27**							
DP	.67**	.54**	.40**	.39**	.56**	-.56**	.47**						
DSS	.47**	.55**	.36**	.42**	.36**	-.27**	.40**	.37**					
SA	.24**	.47**	.40**	.43**	.28**	-.04	.27**	.28**	.33**				
BA	.32**	.56**	.48**	.47**	.38**	-.15**	.30**	.41**	.38**	.56**			
PP	.78**	.67**	.56**	.57**	.54**	-.55**	.59**	.64**	.48**	.38**	.43**		
DP	.43**	.44**	.22**	.28**	.18**	-.20**	.47**	.29**	.43**	.45**	.29**	.51**	
HA	-.46**	-.25**	-.28**	-.32**	-.41**	.66**	-.24**	-.34**	-.12**	.04	-.07*	-.39**	.03

* Significant at $p < .05$; ** significant at $p < .001$ Vulnerable Child (VC); Angry Child (AC); Enraged Child (EC); Impulsive Child (IC); Undisciplined Child (UC); Happy child (HC); Compliant Surrender (CS); Detached protector (DetP); Detaches Self-soother (DSS); Self-aggrandizer (SA); Bully/Attack (BA); Punitive Parent (PP); Demanding Parent (DP); Healthy Adult (HA)

between coping modes (CS, DetP, DSS, SA and BA) was .44, and that between the two dysfunctional parent modes (PP and DP) was .51. None of these results has a value of 1.0; thus, each subscale measures different constructs. Finally, three of the analyzed intercorrelations were nonsignificant despite the high correlations detected (see Table 4): HC and SA; HA and SA; and DP and HA.

Test–retest

Table 5 presents means and SD of the test–retest analyses for each SMI subscale, as did values of the paired samples t-test. The results revealed insufficient test–retest reliability on two subscales: Undisciplined Child and Compliant Surrender mode with $p \geq .004$. However, there was no significant difference between the starting scores and the retest scores in any of the other subscales. Furthermore, as shown in the last two columns of Table 5, both Pearson and Intraclass correlations were all significant at $p < .001$. Most of the subscales presented an adequate correlation ($> .75$), while the lowest value was in the Compliant Surrender subscale (see Table 5). In conclusion, the Italian version of the SMI revealed acceptable consistencies across time.

Table 5 Results test–retest reliability: mean and standard deviation of the baseline scores and retest ($N=50$)

SMI subscales	Baseline mean (SD)	Retest mean (SD)	t (df=49)	p	Test–retest correlation	ICC
Vulnerable child (VC)	1.79 (.60)	1.77 (.68)	.36	.715	.831*	.827*
Angry child (AC)	1.94 (.57)	1.91 (.66)	.39	.697	.766*	.762*
Enraged child (EC)	1.46 (.51)	1.40 (.46)	1.35	.180	.770*	.764*
Impulsive child (IC)	2.07 (.74)	2.01 (.73)	.91	.364	.786*	.787*
Undisciplined child (UC)	2.54 (.89)	2.38 (.72)	2.18	.033	.796*	.764*
Happy child (HC)	4.18 (.82)	3.95 (.91)	2.96	.005	.803*	.771*
Compliant surrender (CS)	2.63 (.50)	2.39 (.53)	3.53	.001	.577*	.503*
Detached protector (DetP)	1.67 (.48)	1.58 (.48)	1.47	.146	.651*	.644*
Detaches Self-soother (DSS)	2.30 (.87)	2.24 (.95)	.64	.520	.787*	.787*
Self-aggrandizer (SA)	2.48 (.54)	2.28 (.66)	3.77	<.001	.813*	.750*
Bully/attack (BA)	1.83 (.45)	1.68 (.43)	2.96	.005	.675*	.633*
Punitive parent (PP)	1.66 (.48)	1.67 (.46)	-.30	.759	.831*	.834*
Demanding parent (DP)	3.07 (.87)	2.92 (.79)	2.07	.043	.828*	.729*
Healthy adult (HA)	4.09 (.55)	3.89 (.75)	2.48	.017	.649*	.590*

Note. * Significant at $p < .001$

Known-Groups Validity

For each group of the sample, Table 6 depicts the average scores and the SD of all the subscales of the SMI. According to the previous results of Reiss et al. (2012), our data showed higher scores in the clinical group than the control group for the maladaptive modes and lower scores in the clinical group than the control group for the adaptive modes. Furthermore, with the exception of the Self-Aggrandizer mode scale, the values of all subscales showed significant linear trends ($p < .001$) over the four groups; this indicated a monotonic increase (linear relationships) of scores in all maladaptive subscales in the following order: from control group ($N=477$), to Axis I patients ($N=67$), to Axis II patients ($N=93$) and to Axis I-II patients ($N=70$). On the other hand, the scores for the adaptive modes decreased monotonically with $p < .001$.

Moreover, the findings showed a significant cubic trend in the following subscales: Angry Child mode, Undisciplined Child mode and Punitive Parent mode with $p < .005$, and Impulsive Child mode and Detached Self-Soother mode with $p < .001$. It seemed that the trend of the average scores followed different directions for these subscales. This was due to a poor difference among the average scores of the Axis I patients group and the Axis II patients group (no significant difference; see Table 2s) and to a high difference between the scores of the control group and the Axis I-II patients (as shown by the large size effect; see Table 6).

In comparing the Axis I-II patients and the control group, it emerged that Cohen's d showed a high effect ($d > .80$) in almost all the subscales (see Table 6). This was not true for the Compliant Surrender, Self-Aggrandizer, Bully, Attack, and Demanding Parent scales, which presented a value of $d > .45$ (average effect). Moreover, Cohen's d comparison, between Axis I patients and the control group on one side and between Axis II patients and the control group on the other side, showed a higher distance from the controls scores for Axis I patients with respect to Axis II patients. In particular, Axis I patients compared to controls showed a Cohen's d of .77, while Axis II patients compared to controls showed a Cohen's d of .40 for the Impulsive Child subscale; only for Axis II patients compare to controls were Cohen's d values $< .30$ (poor effect) for the Bully-Attack and the Demanding Parent subscales. Table 2S in the online supplemental material presents MANOVA outcomes and Bonferroni's multiple comparison between groups. The most noticeable differences were found between the Axis I-II and control groups, with a significant difference for all modes except for SA. Axis I and control groups also showed significant differences for all but 4 modes. Axis II and control groups showed a significant difference in 7 modes. Axis I and Axis II groups did not show significant differences, Axis I-II and Axis I groups showed a significant difference in the VC mode alone, and Axis I-II and Axis II groups showed a significant difference in all 5 dysfunctional Child modes (see Table 2s).

Discussion

This work aimed to evaluate and analyze the short Schema Mode Inventory (Lobbestael et al. 2010) and to contribute to the test's validation in Italian. The study was based on four objectives. First of all, we aimed to verify the multidimensional

Table 6 Means, standard deviations and trend analyses of the Italian version SMI in four subsamples ($N = 707$)

SMI subscales	Control group		Axis I patients		Axis II patients		Axis I-II patients		Linear trend		Cubic trend				
	m	SD	m	SD	m	SD	m	SD	t	p	t	p			
Vulnerable child	1.80	0.73	2.60	1.0	1.04	2.69	1.11	1.10	3.28	1.29	1.8	12.29	<.001**	2.75	.006
Angry child	2.06	0.63	2.62	0.78	.86	2.59	0.86	.78	3.07	1.05	1.44	9.74	<.001**	3.0	.003*
Enraged child	1.44	0.49	1.78	0.88	.61	1.76	0.79	.58	2.20	0.96	1.33	8.46	<.001**	2.51	.012
Impulsive child	2.03	0.70	2.60	0.96	.77	2.32	0.89	.40	3.02	0.99	1.33	8.14	<.001**	4.68	<.001**
Undisciplined child	2.36	0.81	2.87	1.02	.60	2.75	0.92	.47	3.32	1.18	1.10	7.39	<.001**	2.96	.003*
Happy child	3.99	0.75	3.33	0.85	-.86	3.28	0.86	-.92	2.90	1.0	1.38	-9.79	<.001**	-2.32	.020
Compliant surrender	2.40	0.64	2.83	0.84	.64	2.66	0.85	.38	2.86	1.01	.65	3.91	<.001**	2.66	.008
Detached protector	1.68	0.62	2.18	0.99	.74	2.22	1.08	.75	2.53	1.11	1.21	7.74	<.001**	1.83	.067
Detaches self-soother	2.46	0.99	3.27	1.07	.81	2.87	0.93	.42	3.39	0.92	.94	5.77	<.001**	4.34	<.001**
Self-aggrandizer	2.39	0.67	2.68	0.73	.42	2.61	0.73	.32	2.73	0.92	.48	3.10	.002*	1.60	.110
Bully/victim	1.88	0.58	2.10	0.64	.37	2.02	0.70	.23	2.28	0.72	.67	4.37	<.001**	2.12	.034
Punitive parent	1.63	0.51	2.16	0.92	.92	2.13	0.76	.89	2.54	0.97	1.54	9.82	<.001**	3.01	.003*
Demanding parent	2.98	0.82	3.27	1.05	.34	3.21	0.98	.27	3.47	0.96	.58	3.54	<.001**	2.24	.025
Healthy adult	4.28	0.67	3.93	0.77	-.51	3.81	0.65	-.70	3.63	0.84	-1.32	-7.11	<.001**	-.78	.43**

d^1 = Axis I patients vs Control group, d^2 = Axis II patients vs Control group, d^3 = Axis I-II patients vs Control group. * significant at $p < .05$; ** significant at $p < .001$ (Bonferroni's correction used)

structure of the 14-factor test, proposed by Lobbestael et al. (2010), in the Italian context. Second, we wanted to verify the higher level structure of modes (Young et al. 2003; Lobbestael et al. 2007). Third, we evaluated the reliability properties and the relationships among SMI subscales. Finally, we analyzed the instrument's criterion validity.

The results from CFA showed that the 14-factor model organization is in accordance with the results emerging from previous international verifications.

As for the second objective, the higher-order structure proposed by Young (1990) was confirmed, as shown by fit indexes. The model with one superordinate factor also showed good fit indexes, with the BIC showing a better fit for Young's (1990) original proposal. The analysis aiming to combine the HA and HC functional modes was not confirmed. The fit indexes of the Italian version of the SMI are very similar to those observed in the Dutch (Lobbestael et al. 2010) and in the German (Reiss et al. 2012) versions but slightly different from those in the Danish version (Reiss et al. 2015). From a clinical point of view, it is preferable to use the 14 first-level model with the 4 higher categories (Child, Coping, Parent, Adult), which is also the model with the best fit indexes.

The third objective consisted of analyzing the internal reliability of each of the 14 subscales in the instrument. Cronbach's alpha has been calculated for each subscale. Moreover, mean inter-item correlation and mean item loading were obtained. The measurements that emerged revealed a good internal reliability of the SMI. The α for the Bully and Attack subscale was only sufficient, highlighting a low internal consistency between the nine items in that subscale. In particular, item 23, "If you let other people mock or bully you, you are a loser", and item 98, "I mock or bully other people", showed an insufficient item-scale correlation. Eventual surveys may eliminate one of the two items to increase alpha value in this subscale. This result is different from those found in the Danish (Reiss et al. 2015), German (Reiss et al. 2012) and Dutch versions (Lobbestael et al. 2010), in which the α coefficient showed good reliability. Moreover, we found that items had a slightly lower intercorrelation average when compared to previous verifications. The items' medium-weight is suitable. A good test-retest stability of the instrument emerged from the paired sample t-test analysis.

Almost all of the correlations between subscales were significant, but none showed a value of $< .90$. This means that the subscales measure different constructs even if they identify similar characteristics in the patient. For example, the Detached Protector and the Detached Self-soother turned out to be correlated; both of them refer to the construct of emotional retreat, but very different behavioral patterns emerged (Lobbestael et al. 2010). Finally, the adaptive mode subscales presented a considerable negative correlation with the maladaptive mode subscales; this is in accordance with the theoretical model of ST. For example, maladaptive modes that refer to emotional dysregulation, unhealthy behaviors, and impulsive-oriented behaviors (e.g., Punitive Parent or Impulsive Child mode) are related negatively with modes that refer to the ability to cope in healthy and emotionally regulated ways, such as the healthy adult mode (e.g., Healthy Adult and Happy Child).

Vulnerable Child and Punitive Parent modes show high correlation. The schema therapy model describes how the activation of the Punitive Parent

mode, characterized by a stereotyped negative self-esteem, gives rise to guilt and punitive modalities against the Vulnerable Child mode. The strong correlation between Vulnerable Child and Punitive Parent found in this study seems to confirm this, as well as the strong correlation between Enraged Child and Angry Child. In fact, similar stimuli usually trigger these modes, which then cause the activation of behavioral patterns with the same relational purpose. In the same direction, we see that Angry Child and Punitive Parent show a strong correlation. According to the ST model, the activation of the Angry Child is consequent to the activation of the Vulnerable Child and Punitive Parent. The interpretive pattern of ST is confirmed further by the strong correlation between the Happy Child and Healthy Adult modes. Functional modes are interrelated in this model. On the opposite side, as expected, Healthy Child and Vulnerable Child correlate negatively. This pattern of correlation provides further evidence to the construct validity of the SMI.

We do not observe any correlation between both functional modes, Happy Child and Healthy Adult, and the dysfunctional Self-Aggrandizer coping mode. We know from clinical testing that some patients have exaggeratedly low scores or exaggeratedly high scores in the Self-Aggrandizer mode, which probably led to a close to zero correlation, since it is bound to be negative in some cases and positive in others. From clinical experience, we can affirm that the Self-Aggrandizer influences the subject's resilience in a positive way when it is in the range of average scores. Along with clinical experience, it is evident that there is low self-reliance in the subject when this score is very low (Bernstein et al. 2007). Further studies are needed to confirm this hypothesis. This brings us to a consideration: the SMI does not consider enough positive modes. The Healthy Adult and Happy Child modes are the main adaptive modes, but clinical experience highlights the existence of other functional co-operational modes (i.e., healthy parental modes, functional coping modes, etc.) This is clearly a strong limit to this model. The SMI test is based on a clinical model that uses the diathesis stress model interpretation framework (Lionetti et al. 2014). This model sees pathology as a relationship between a disadvantaged environment and a presumed vulnerability. It focuses on conditions that favor the emergence of pathology. Indeed, ST is a model born from clinical practice. Its blind point is not showing that people who develop pathologies do not just show vulnerability but also what is referred to as extreme susceptibility or a different biological sensitivity (Belsky et al. 2007). Individuals do not just vary in the degree to which they are vulnerable to the negative effects of adverse experiences; more generally, variations in their developmental plasticity can be found. Different observations have shown that these extremely susceptible subjects developed above-average social, psychological and cognitive abilities in environments that boosted development. On the other hand, subjects that the diathesis-stress model described as resilient did not show substantial improvements in their abilities, even when exposed to an appropriate environment. These subjects are described as fixed individuals in this new framework. In this case, the SMI does not allow for us to grasp the difference between highly susceptible and fixed subjects because it does not measure positive modes but instead only the area found in the diathesis-stress model. In line with these new hypotheses, it might be important to focus clinical attention not only on maladaptive schemas

or dysfunctional modes but also on the patient's general adaptive ability and consequently on positive schemas and functional modes.

As a fourth hypothesis, the criterion validity of the Italian SMI has given similar results to the Dutch study (Lobbestael et al. 2010), in which the instrument's criterion validity was examined through the analysis of the averages of each subscale (14) in the three analyzed groups: controls, Axis I patients and Axis II patients. The results showed a significant positive linear trend in each SMI subscale and a negative quadratic trend for the Angry Child and Detached Protector subscales. Finally, a positive quadratic trend emerged from the Happy Child subscale. Known-group validity has been tested on four groups of participants in our study: controls, Axis I patients, Axis II patients, and patients with both Axis I and Axis II diagnoses. According to the polynomial contrast's analysis with which the factor group has been evaluated, a significant positive linear trend has emerged in almost every SMI's subscale, apart from the Self-aggrandizer scale; this last result is consistent with the findings of the German study (Reiss et al. 2012), in which this subscale does not determine a distinction between psychiatric patients and the control group. Furthermore, a cubical trend was found in four subscales: Impulsive Child and Demanding Parent, Angry Child, Impulsive Child and Punitive Parent modes. The group of patients with both Axis I and Axis II diagnoses presented higher scores than controls. When a patient shows symptoms from Axis I together with symptoms from Axis II, he/she usually show global functioning, as measured by Global Assessment of Functioning, which is much worse when compared to patients who only show symptoms from one of the two axes (Bodlund et al. 1994; Denys et al. 2004; Miller et al. 2007; Tungström et al. 2005; Zanarini et al. 2004). These data confirm this observation, which has already been shown in literature, and confirm how important it is for the next validation to differentiate patients using their disorders as a criterion, specifying the eventual presence of comorbidity. In addition, the group with disorders in both axes presented higher scores than patients with diagnosis in only one axis in all Child modes and in the Punishing Parent mode (see Table 2s). It is well known in ST that Punishing Parent mode is usually the introjection of dysfunctional relationships with significant figures and that this mode causes most psychological complaints in patients when associated with vulnerability modes (Young 2005; Lobbestael et al. 2005). This brings a higher level of emotional dysregulation in subjects (Dadomo et al. 2016; van Zutphen et al. 2015).

There was no significant difference between the three groups of patients in the dysfunctional modes subscales, with the exception of Detached Self-soother and Bully and Attack, where patients with both Axis I and Axis II diagnoses had higher scores than Axis II patients. Demanding Parent and Healthy Adult also showed no significant differences between the three groups of patients.

The variability in results about the SMI's criterion validity could be due to the insertion of patients with both Axis I and Axis II diagnoses, which have not been studied in previous research. Overall, the criterion effectiveness of the Italian SMI turned out to be appropriate.

The forthcoming developments for the SMI's validation can consider other new mode configurations to simplify the distinction in the assessment phase of patients with PD. Bernstein et al. conducted a study in 2007 in which they suggested

inserting other representative subscales of these modes: Predator, Conning-Manipulative and Healthy Parent. This brings the need for a statistic evaluation of the effect these new modes will have on the instrument's discriminant effectiveness, as Bamelis et al. (2011) did while developing the SMI 2. On the other hand, clinical application in a complex situation such as couple's therapy (Simeone-DiFrancesco et al. 2015) requires a simplification of the model. A middle ground between the necessities of research and clinical work must be found. In conclusion, the present study produced results that indicate the Italian version of the SMI as a useful tool for the assessment of modes in ST for both clinicians and researchers. This study also contributes to the empirical validation of core concepts in ST while also contributing to the diffusion of the SMI as a standardized assessment instrument of schema modes in another language.

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Compliance with Ethical Standards

Conflict of interest Author Panzeri, Author Fontanesi, Author Busà, Author Ronconi, Author Carmelita, and Author Dadomo declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study. None of the participant had a LAR.

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