

Italian validation of the *Clinical Outcomes in Routine Evaluation-10* (CORE-10): a short measure for routine outcome monitoring in clinical practice

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ABSTRACT

The customization of the intervention using patient feedback is an evidence-based practice aimed at the continuous evaluation, during treatment, of the patient's change at a clinical level. There are few easy-to-use tools for common assessment of psychological distress, designed to be used for screening and during treatment to monitor progress. The *Clinical Outcomes in Routine Evaluation-10* (CORE-10) is definitely one of them. Thus, the aim of the present study was to examine the psychometric properties of the Italian version of the CORE-10. A sample of 548 participants (females, $N=463$, 84.5%; mean age 23.29 ± 7.21 years) was recruited in the study and filled out a battery of measures. The internal validity of the CORE-10 was investigated through a confirmatory factor analysis which evidenced a good fit to the data, suggesting a unidimensional factorial structure of the measure. Further, the scale had a good internal reliability and was significantly associated with other measures of distress, interpersonal problems, well-being, and insecure attachment. Finally, it showed excellent diagnostic accuracy, as well as intrinsic and post-test diagnostics. Given its validity and reliability, the CORE-10 may be adopted by Italian-speaking psychotherapists and researchers to evaluate the outcomes of mental health interventions as well as to track the session-to-session changes over time in psychological distress among patients.

Key words: CORE-10; Italian validation; psychometric properties; routine outcomes evaluation.

Introduction

Previous literature and clinical practice suggest that a routine evaluation of outcomes in psychological therapies has several advantages. Reported outcome measures may help practitioners and patients to identify difficulties in specific domains, which may otherwise have been missed, building a shared, more comprehensive, understanding of the patient's distress (Lambert *et al.*, 2018). From the therapist's perspective, the monitoring of outcomes is essential to build practice-based evidence interventions and guarantee informed decision-making (Barkham, Hardy, & Mellor-Clark, 2010). A routine evaluation of outcomes helps therapists in identifying possible problematic responses to treatment, increasing the patient-therapist collaboration to overcome such unexpected results (Lambert *et al.*,

2018). In turn, providing feedback and discussing the therapy progress regularly seems to improve the patient's engagement (De Jong *et al.*, 2014; Lambert *et al.*, 2002; 2003).

A recent meta-analysis on the effect of routine outcome monitoring in psychotherapy showed a small to moderate effect on patients' progress, reducing deterioration rates and increasing the chance of clinically significant and reliable change rates in clients who were predicted to have a poor outcome (Lambert *et al.*, 2018). Thus, since the evaluation of outcomes is relatively effortless, the benefits of a brief, regular monitoring may overcome the possible limitations, despite the effect reported in the mentioned meta-analysis was not huge. Routine outcome measurement systems are wide-spread and commonly used in healthcare services in several countries, in which psychological therapies are often refunded by insurance agencies and/or delivered in the context of public facilities that are interested in receiving accurate and objective feedback on the services provided. However, a systematic outcome evaluation is not very common in Italy (Chiappelli *et al.*, 2008; Gallo & Rucci, 2000; Lomazzi *et al.*, 1997), where therapy is often paid by the patient and not by insurance companies. On the other hand, therapists who would like to implement a routine evaluation of outcome may be hampered by the limited availability of gold-standard, easy, and quick instruments validated in Italian.

Worldwide, the *Partners for Change Outcome Management System* (PCOMS; Duncan, 2012) and the *Outcome Questionnaire* (Lambert *et al.*, 2004) are the most used instruments for the outcome monitoring in the clinical setting. The PCOMS (Duncan, 2012) is an established and widespread protocol for the outcome measurement, combining several instruments assessing therapy progress and alliance in both adults and children. Specifically, the embedded *Outcome Rating Scale* (ORS, Miller *et al.*, 2003) is a simple, four-item session-by-session measure designed to assess areas of life functioning known to change as a result of therapeutic intervention (*i.e.*, personal or symptom distress, interpersonal well-being, social role, and overall well-being). However, the use of the PCOMS and the included instruments requires the payment of a fee, possibly discouraging practitioners and especially those not operating in healthcare services (*i.e.*, covering the cost of these instruments). Also, no previous validation of these instruments is available in Italian. The *Outcome Questionnaire 45* (OQ-45) is a 45-item tool investigating three domains central to mental health: subjective discomfort, interpersonal relations, and social role performance, proven of strong reliability and validity (Lambert, 2010). It was previously validated in Italian language (Chiappelli *et al.*, 2008); however, it is licensed and possibly too long for a session-by-session administration.

The *Clinical Outcomes in Routine Evaluation-Outcome Measure* (CORE-OM; Evans *et al.*, 2002) is a free tool for outcomes monitoring, which is widely used and shown to be reliable in a range of settings (Barkham *et al.*, 2001; Evans *et al.*, 2003; Shepherd *et al.*, 2005). The full format includes 34 self-report items covering four domains of possible distress and dysfunction: i) subjective well-being, ii) problems/symptoms, iii) life functioning and iv) risk. The average score obtained across the items is informative about the level of overall mental health or distress, as defined by normative cut-offs. To date, the CORE-OM has been translated to over 30 languages, including Swedish (Elfström *et al.*, 2013), Chinese (Zhang *et al.*, 2020) and Italian (Palmieri *et al.*, 2009), showing excellent psychometric properties.

The CORE-OM is mostly used at the beginning and end of

therapy, but a shortened 10-item version of the instruments has been validated [*i.e.* the *Clinical Outcomes in Routine Evaluation-10* (CORE-10); Barkham *et al.*, 2013]] for session-by-session administrations or to be used in time-limited settings. In their original validation study, Barkham and colleagues (2013) showed that the CORE-10 had good psychometric properties, including good internal consistency, a single-factor structure, and a good convergent/divergent validity with other measures of depression, general/social/close relationships, and self-harm risk. Its total score was associated with very large effects $r > 0.90$ with that obtained from the CORE-OM, thus suggesting that both measures investigate the same latent factor. Finally, Barkham and colleagues (2013) provided both a clinical cut-off for general psychological distress (*i.e.*, a score ≥ 11.0) and a reliable change index (*i.e.*, a change score ≥ 6).

Despite its potential usefulness, currently no Italian validation is available for the CORE-10. The availability of a shorter and free tool for routine outcomes measurements may encourage practitioners in monitoring patients' progresses in the clinical setting; also, it may be used in research on therapies effectiveness, promoting the development of evidence-based practices. Thus, the aim of this study is to probe the psychometric properties of the Italian translation of the CORE-10, providing a validated version of the instrument to be easily used in both clinical and research settings.

Materials and Methods

Participants

A total of 548 participants (female $N=463$, 84.5%; mean age 23.29 ± 7.21 years) were consecutively recruited between October 2021 and January 2022 for this validation study. Most of the sample had a high school diploma ($N=493$; 90%), was unmarried ($N=500$; 90.6%), and was living with parents ($N=435$; 79.6%). Inclusion criteria included the following: i) at least 18 years of age; ii) providing consent to participate; iii) understanding of spoken and written Italian.

Procedure

Data collection occurred between October 2021 and January 2022, through an anonymous online survey. Participants were recruited starting from university students attending undergraduate courses at University of Bergamo, and -through a snowball sampling procedure- asking them to forward the invitation to fill out the survey to friends and relatives. Further, we placed notices on social media inviting individuals to complete a battery of questionnaires. Those who agreed to participate (*i.e.*, provided informed consent) were subsequently redirected to a webpage detailing the overall aims of the research and the names and contact information of the researchers. Participants then had access to a demographic survey and a battery of questionnaires. The study was conducted in accordance with ethical standards and approved by the local ethics committee.

Measures

Socio-demographics

The survey included an *ad-hoc* sociodemographic survey, which investigated sex, age, relationship status, and educational level of the study participants.

Psychological distress

The CORE-10 (Barkham *et al.*, 2013), is a brief 10-items measure of psychological distress developed for routine use in practice settings. The CORE-10 is a shortened version of the 34-item CORE-OM (Barkham *et al.*, 2001; Evans *et al.*, 2002), and taps into three domains: i) *problems*: depression (2 items), anxiety (2 items), physical (1 item), and trauma (1 item); ii) *functioning*: general functioning (1 item), social functioning (1 item), and close relationships (1 item); and iii) *risk*: to self (1 item).

Two items (*i.e.*, item 2 ‘I have felt I have someone to turn to for support when needed’ and item 3 ‘I have felt able to cope when things go wrong’) are worded positively and thus are reverse scored. Items are rated on a 5-point Likert-type scale (0 = *not at all* to 4 = *most or all of the time*), and higher total scores (*i.e.*, the sum of all items, with a range from 0 to 40) indicate greater distress. In this study, the McDonald’s Omega was good ($\omega=0.81$).

The Italian version of the *Depression, Anxiety and Stress Scale-21* (DASS-21; Lovibond & Lovibond, 1995; Bottesi *et al.*, 2015) is a 21-item self-report measure of depression, anxiety and stress. The DASS-21 is composed by three subscales (depression, anxiety and stress, each composed by 7 items). Items are rated on a 4-point Likert-type scale (0 = *did not apply to me at all* to 3 = *applied to me very much, or most of the time*). Once summed, the three subscales provide an overall index (range 0-43), with a higher total score indicating a greater emotional distress. Previous studies (*i.e.*, Bottesi *et al.*, 2015) showed that the questionnaire had good internal validity, reliability and good convergent/divergent validity. In this study, the McDonald’s Omega was excellent ($\omega=0.92$).

The Italian version of the OQ-45 (Lambert *et al.*, 1996; Lo Coco *et al.*, 2008), a 45-item self-report measure of psychological distress. The OQ-45 is composed of three subscales, namely *Symptom Distress* (25 items), *Interpersonal Relations* (11 items), and *Social Role* (9 items), which scores can be summed into a total score (range 0-180). Items are rated on a 5-point Likert-type scale (0 = *rarely* to 4 = *almost always*). Higher total scores indicate more severe distress and functional impairment. Previous studies (*i.e.*, Lo Coco *et al.*, 2008) showed that the questionnaire had good psychometric properties. In this study, McDonald’s Omega was excellent ($\omega=0.92$).

Interpersonal problems

The Italian version of the *Inventory of Interpersonal Problems 32* (IIP-32; Horowitz *et al.*, 1988; Lo Coco *et al.*, 2018) is a questionnaire consisting of 32 items describing dysfunctional interpersonal behaviors that the responder identifies as “difficult to do” (*i.e.* behavioral inhibitions) or “doing too much” (*i.e.* behavioral excesses). Items are rated on a 5-point Likert-type scale (0 = *not at all* to 4 = *extremely*). IIP-32 is composed by eight subscales, namely domineering/controlling (PA), vindictive/self-centered (BC), cold/distant (DE), socially inhibited/avoidant (FG), non-assertive (HI), overly accommodating/exploitable (JK); self-sacrificing/overly nurturant (LM), and intrusive/needy (NO), each consisting of four items. The sum of the 8 subscales provides an overall index (range 0-128), with higher scores indicating greater interpersonal problems. Previous studies (*i.e.*, Lo Coco *et al.*, 2018) showed that the questionnaire had good internal validity, reliability and good convergent/divergent validity. In this study, the McDonald’s Omega of the total score was good ($\omega=0.87$).

Well-being

The Italian version of the *World Health Organization-Five Well-Being Index* (WHO-5; WHO, 1998) is a short self-report measure consisting of 5 items and which evaluates the current mental well-being of the subject. Items are rated on a 6-point Likert-type scale (0 = *at no time* to 5 = *all of the time*). The total score is computed as a sum of all the completed items (range from 0 to 25) with higher total scores indicating greater mental well-being. The measure evidenced good psychometric properties (*i.e.*, Topp *et al.*, 2015). In this study, the McDonald’s Omega was good ($\omega=0.84$).

Satisfaction with life

The Italian version of the *Satisfaction with Life Questionnaire* (SwL; Pavot & Diener, 1993; Di Fabio & Gori, 2016) is a 5-items self-report measure of subject’s life satisfaction. Items are rated on a 7-point Likert scale (1 = *strongly disagree* to 7 = *strongly agree*). The total score is computed as a sum of all the completed items (range from 5 to 35) with higher total scores indicating greater subject’s life satisfaction. The measure evidenced good construct validity and internal reliability (Di Fabio & Gori, 2016). In this study, the McDonald’s Omega was good ($\omega=0.87$).

Psychological functioning

The *Complementary Measure of Psychotherapy Outcome* (COMPO-12; Chui *et al.*, 2021) is a self-report questionnaire consisting of 12 items that evaluates the psychological functioning deemed important by clients and therapists. A multi-step strategy was adopted for the translation of the COMPO-12 starting from the original English version developed by Chui (2021). The scale was translated from English into Italian separately by two Italian authors of this study (see Harkness *et al.*, 2004 for detailed information on the translation procedure). The resulting Italian version was then back translated into English by a native speaker to establish the comparability and to resolve any discrepancies. Items are rated on a 7-step Likert scale (1 = *strongly disagree* to 7 = *strongly agree*). Clinicians and researchers can use the COMPO-12 total score as a global measure (range 12-84), as well as the COMPO-12 subscale scores to understand different aspects of clients. The COMPO-12 evidenced good construct validity and internal reliability (Chui *et al.*, 2021). In this study, the McDonald’s Omega was good ($\omega=0.81$).

Attachment insecurity

The Italian version of the *Experiences in Close Relationships-12* (ECR-12; Lafontaine *et al.*, 2015; Brugnera *et al.*, 2019) is a 12-item self-report measure of attachment to romantic partners. The ECR-12 measures two dimensions of attachment to romantic partners, namely attachment avoidance (6 items) and attachment anxiety (6 items). Items are rated on a 7-point Likert-type scale (from 1 = *completely false* to 7 = *completely true*), and higher subscale scores (range 1-7) indicating greater attachment avoidance or attachment anxiety with romantic partners. Previous studies (*i.e.*, Lafontaine *et al.*, 2015; Brugnera *et al.*, 2019) showed that the questionnaire had good internal validity, reliability and good convergent/divergent validity. In this study, the McDonald’s Omegas were good to excellent ($\omega=0.90$ for attachment avoidance, $\omega=0.84$ for attachment anxiety).

Statistical analysis

Initially, data were examined through simple descriptive statistics, such as means, standard deviations, frequency, and percentages. No missing data were observed. We then tested normality assumptions for each variable used in this study, including the CORE-10 items. Univariate normality was tested examining the skewness and kurtosis values (deemed as abnormal if $> |1|$ and $|3|$, respectively; Kim, 2013). All variables were normally distributed, except for age and item 6 of the CORE-10, which were strongly skewed (Table 1). Further, we tested for the presence of multivariate outliers examining (for each participant) if the chi-square value associated with the Mahalanobis distance was greater than the critical χ^2 value at a significant threshold of .05 (Tabachnick & Fidell, 2007). Twenty-nine outliers were identified and subsequently removed from the analyses. We finally examined if the CORE-10 items had a multivariate normal distribution *via* a Mahalanobis' distance-based graphical inspection (Nor, 2015), whose results were suggestive of multivariate normality.

A Confirmatory Factor Analysis (CFA) was performed on the polyconic correlation matrix to test the supposedly unidimensional structure underlying CORE-10 items (Barkham *et al.*, 2013). Parameters were estimated with the Weighted Least Squares Mean and Variance (WLSMV) estimation method for ordinal data, which is robust to non-normally distributed variables (such as in the case of Item 6). Model fit was deemed as optimal based on the following metrics and cut-offs: χ^2/DF ratio (CMIN/DF; <2), comparative fit index (CFI; ≥ 0.95), Tucker-Lewis index (TLI; ≥ 0.95), root mean square error of approximation (RMSEA; ≤ 0.08), and standardized root mean square residual (SRMR; ≤ 0.08 ; Schermelleh-Engel, Moosbrugger, & Müller, 2003; Hu & Bentler, 1999).

Internal reliability of the CORE-10 was tested through McDonald's ω and Spearman-Brown's split-half coefficient. As for construct validity, the association between CORE-10 scores and age was assessed by means of a Spearman's correlation, whilst that with sex and education through *F*-tests. Further, the association between CORE-10 and all measures used in this study (OQ45, DASS21, IIP-32, WHO-5, SWL, COMPO-12 and ECR-12) was tested via Pearson's *r* correlation coefficients, whose resulting *p*-values were corrected with the Bonferroni's method to control for the inflation of type-I error rates (Holm, 1979).

Finally, based on Aiello *et al.*'s (2022) approach, the diagnostic efficiency of the CORE-10 was examined by means of a

receiver-operating characteristics (ROC) analyses against a positive state operationalized as the combination of a DASS-21 score $>90^{\text{th}}$ percentile and a WHO-5 score $<10^{\text{th}}$ percentile of the empirical distribution (judged as indexing high levels of psychological distress and low subjective psychological well-being, respectively). Sensitivity (Se), specificity (Sp), positive and negative likelihood ratios (LR+; LR-) were derived at the optimal cut-off identified *via* Youden's *J* statistics.

All effect sizes were computed and interpreted according to guidelines (Cohen, 1988). Analyses were run on MPLUS Version 8.4 (Muthèn & Muthèn, 2017), jamovi 2.3.12 (<https://www.jamovi.org/>) and R 4.1.0 (<https://www.r-project.org/>). The significance level was set at $\alpha=0.05$.

Results

Tables 1 and 2 report descriptive statistics of all CORE-10 items and of all measures used in this study, respectively. Further, item response distributions for each item are reported in the Supplementary Materials.

The CFA showed that CORE-10 items optimally met a unidimensional structure [$\chi^2=87.792$ (35), $p<0.001$, CMIN/DF=2.508; CFI=0.983; TLI=0.978; SRMR=0.035; RMSA=0.052 (0.039-0.066)], with all items significantly loading on the underlying factor (all $p<0.004$; see Figure 1 for betas and residual variances). As for the internal consistency of this scale, McDonald's ω was 0.81, slightly benefiting only from the potential drop of item 2 (putative McDonald's $\omega=0.83$); inter-item correlations ranged from 0.33 to 0.73, without item 2 being looked at – which yielded an inter-item correlation of 0.13. Finally, Spearman-Brown's split-half coefficient was 0.79.

At $\alpha_{\text{adjusted}}=0.006$ ($\alpha_{\text{adjusted}}=0.05/k$, where *k* is equal to the number of comparisons, *i.e.* $k=8$), CORE-10 scores were positively associated with the DASS-21 [$r(548)=0.82$; $p<0.001$], OQ-45 [$r(548)=0.76$; $p<0.001$], IIP-32 [$r(548)=0.54$; $p<0.001$] and the anxiety [$r(548)=0.30$; $p<0.001$] and avoidance [$r(548)=0.27$; $p<0.001$] subscales of the ECR-12, whereas negatively with the WHO-5 [$r(548)=-0.62$; $p<0.001$], COMPO-12 [$r(548)=-0.45$; $p<0.001$] and SWL [$r(548)=-0.50$; $p<0.001$]. All effects were medium-to-large.

No associations were detected between the CORE-10 and age [$r_s(548)=-0.07$; $p=0.116$], sex [$F(1,544)=2.09$; $p=0.149$, partial $\eta^2=0.004$] or education [$F(1,538)=1.11$; $p=0.353$, partial $\eta^2=0.002$], with trivial effects.

Table 1. Descriptive for *Clinical Outcomes in Routine Evaluation-10* (CORE-10) items (N=548).

CORE-10 Items	Mean±SD	Range	Skewness	Kurtosis
Item 1	2.09±1.03	0-4	-0.142	-0.591
Item 2R*	1.65±1.10	0-4	0.223	-0.714
Item 3R*	1.43±0.85	0-4	0.327	-0.139
Item 4	1.41±1.14	0-4	0.438	-0.592
Item 5	0.76±1.03	0-4	1.148	0.264
Item 6	0.11±0.36	0-2	3.45	12.0
Item 7	1.35±1.18	0-4	0.482	-0.765
Item 8	1.10±1.11	0-4	0.745	-0.405
Item 9	1.49±1.04	0-4	0.320	-0.537
Item 10	1.34±1.16	0-4	0.463	-0.857

SD, standard deviation. *Reversed-scale item.

At an optimal cut-off of >20 ($J=0.86$), the CORE-10 showed excellent diagnostic accuracy [$AUC=0.97$; $SE=0.01$; $95\%CI(0.95, 0.99)$], as well as intrinsic ($Se=0.94$; $Sp=0.92$) and post-test diagnostics ($LR+=11.64$; $LR-=0.06$). According to such a cut-off, 13.2% of the sample was classified as obtaining an abnormal score on the CORE-10.

Discussion

This study provides Italian practitioners and clinical researchers with the adaptation and standardization of the CORE-10, a practicable screener for psychological distress that may be easily used in both clinical and research settings for routine outcome monitoring.

The Italian version of the CORE-10 proved to be i) underpinned by a mono-factorial structure, ii) internally reliable and iii) to have both convergent and divergent validity, being also iv) featured by excellent diagnostics as to the detection of psychological distress.

First, the Confirmatory Factorial Analysis evidenced a good fit to the data, suggesting a unidimensional factorial structure. That is, psychological distress as operationalized by CORE-10 may be considered a combination of three domains, namely psychological problems, functional impairments and risk to self (Barkham *et al.*, 2013). Similarly, the internal reliability of the scale was good, and this suggests that all items were closely related to each other. Of note, Item 2 (“*I have felt I have someone to turn to for support when needed*”) had the lowest loading among all others, suggesting that the variance of this item was not adequately captured by the latent dimension “distress”. In fact, there is still an open debate in the literature about whether this item should be considered a part of the psychological distress factor or, rather, a part of social well-being (*i.e.*, Fairhurst *et al.*, 2014).

Our results showed a good construct validity of the instrument. Indeed, we found a positive and significant association between the CORE-10 total score and other well-known measures of psychological distress (*i.e.* DASS-21 and OQ-45) and interpersonal problems (IIP-32), with large effects; similarly, we observed a negative and significant correlation with overall well-being (WHO-5), psychological functioning (COMPO-12) and satisfaction with life (SWL), with medium-to-large effects. Taken together, these findings suggest that an increasing level of psychological distress as evaluated by the CORE-10 corresponds

to a worse psychological functioning and quality of life. Finally, psychological distress – as indexed by greater CORE-10 total scores – was significantly and positively associated (with a small effect) with anxious and avoidant attachment, both considered a risk factor for both the onset and the maintenance of subclinical psychological suffering and psychopathology (Mikulincer & Shaver, 2012). No association was reported between CORE-10 scores and sex, age and education, suggesting that this measure is largely unrelated from sociodemographic variables, at least in our sample; thus, the possibility of a wide-spread use of the instrument in both the clinical and research setting.

Finally, the Italian version of the CORE-10 showed excellent diagnostic accuracy, as well as intrinsic and post-test diag-

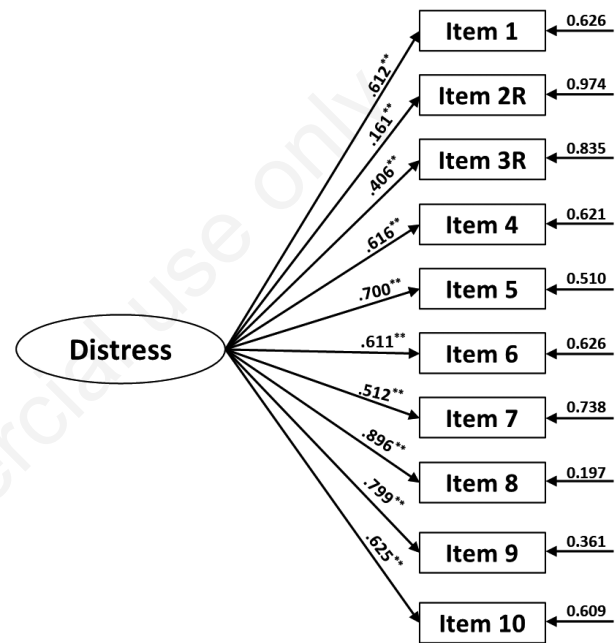


Figure 1. Standardized estimates and residual variances of the Clinical Outcomes in Routine Evaluation-Outcome Measure (N=548). Items 2 and 3 were reversed for ease of interpretation. Residual variances were computed as remainders after model estimation. ** $p<0.001$.

Table 2. Descriptive for all measures used in the study (N=548).

Variable	Mean±SD	Range
CORE-10	12.73±6.11	(1-33)
DASS-21	17.49± 10.10	(0-53)
OQ-45	55.98±19.59	(9-116)
IIP-32	38.67±15.83	(5-87)
WHO-5	13.11±4.34	(0-23)
COMPO-12	63.24±8.68	(31-84)
SWL	20.90±6.05	(5-35)
ECR-12 anxiety	4.64±1.35	(1-7)
ECR-12 avoidance	2.48±1.26	(1-7)

CORE-10, Clinical Outcomes in Routine Evaluation-Outcome Measure; DASS-21, Depression, Anxiety & Stress scale; OQ-45, Outcome Questionnaire 45; IIP-32, Inventory of Interpersonal Problems; WHO-5, World Health Organization-Five Well-Being Index; COMPO-12, Complementary Measure of Psychotherapy Outcome; SWL, Satisfaction with Life questionnaire; ECR-12, Experiences in Close Relationships scale.

nostics. An optimal cut-off of 20 was found to be critical for identifying highly distressed individuals with a poor well-being. In this regard, from a clinical perspective, it is interesting to note that more than 10% of the participants scored above the psychopathological cut-off. The prevalence of severe psychological distress in our sample was similar to that of age-matched, nationally representative samples of emerging adults in the US (11.99% in 2017; Twenge *et al.*, 2019).

Concerning the possible limitations of the present study, we may mention that we did not assess the test-retest stability or examine social desirability effects. Also, we may note that the large majority of the sample was composed by students, possibly limiting the generalizability of the results to other populations (including the clinical one).

Conclusions

To conclude, this study provides the first evidence on the psychometric robustness of the Italian version of the CORE-10 as a brief and reliable measure of psychological distress, encouraging therapists to adopt this instrument for effective routine outcomes evaluation in both the clinical and research setting.

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