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Development and psychometric validation of the Clinical Assessment Interview for Negative Symptoms (CAINS)

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ABSTRACT

Progress in the development of new pharmacological and psychosocial treatments for the negative symptoms of schizophrenia is impeded by limitations of available assessment instruments. The multi-site Collaboration to Advance Negative Symptom Assessment in Schizophrenia (CANSAS) was established to develop and validate a new clinical rating scale using a transparent, iterative, and data-driven process. The Clinical Assessment Interview for Negative Symptoms (CAINS) was designed to address limitations of existing measures and assess consensus-based sub-domains, including asociality, avolition, anhedonia, affective blunting, and alogia. The structure and psychometric properties of the CAINS were evaluated in a sample of 281 schizophrenia and schizoaffective outpatients at four sites. Converging structural analyses indicated that the scale was comprised of two moderately correlated factors — one reflecting experiential impairments (diminished motivation and enjoyment of social, vocational, and recreational activities) and one reflecting expressive impairments (diminished non-verbal and verbal communication). Item-level analyses revealed generally good distributional properties, inter-rater agreement, discriminating anchor points, and preliminary convergent and discriminant validity. Results indicate that the CAINS is a promising new measure for quantifying negative symptoms in clinical neuroscience and treatment studies. Results guided item modification or deletion, and the reliability and validity of the revised, shorter version of the CAINS is in the final phase of development within the CANSAS project.

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1. Introduction

Negative symptoms substantially impede functional recovery for people with schizophrenia (Kirkpatrick et al., 2006). Despite their clinical significance, current treatments do not adequately address negative symptoms — there are not yet any medications with a specific indication for negative symptoms and psychosocial interventions show similarly limited benefits (Leucht et al., 1999; Montgomery and Zwieten-Boot, 2006). To address this critical treatment need, the NIMH-Negative Symptom Consensus Development Conference (Kirkpatrick et al., 2006) recommended that the field required a new negative symptoms measure that can be productively used in pharmacological trials. The Collaboration to Advance Negative Symptom Assessment of Schizophrenia (CANSAS) was established to develop and validate a "next-generation" clinical rating scale by following data-driven, iterative, and transparent process (Blanchard et al., 2011). This report describes the psychometric evaluation of a beta version of the Clinical Assessment Interview for Negative Symptoms (CAINS) in a large outpatient sample. This effort is unlike any other scale development project to date in that it includes a large and diverse patient population and adopts a comprehensive empirical approach to item generation, selection, and retention.

The CAINS was designed to address limitations of existing instruments (Horan et al., 2006; Blanchard et al., 2011) and assess the five consensus negative symptom sub-domains (Kirkpatrick et al., 2006). Ratings of asociality, avolition, and anhedonia are based on interviewees' reported subjective experiences of motivation and emotion, as well as frequency of actual engagement in relevant activities. Asociality assesses the degree to which close social bonds are valued and desired, and frequency of social interactions. Avolition assesses level of interest and motivation, and initiation and persistence of behavior. Anhedonia assesses experience and frequency of consummatory pleasure and anticipatory pleasure. The final two domains are rated based on observable behaviors throughout the interview. Blunted affect ratings also include prompts to elicit positive and negative emotions. Ratings for alogia include measures of speech output.

A feasibility study of an early version of the scale (Forbes et al., 2010) demonstrated good internal consistency and inter-rater agreement, and

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very good convergent and discriminant validity with other symptom and functional outcome measures. However, several areas needed refinement, including skewed and restricted range of anhedonia items, low inter-item correlations in asociality and avolition domains, marginal inter-rater agreement for items in alogia and avolition domains, and difficulties distinguishing among anchor points for several items.

We report here a comprehensive psychometric evaluation of the revised CAINS in a large, diverse sample of outpatients with schizophrenia or schizoaffective disorder based on recommendations that clinically stable patients are preferred for negative symptom treatment development studies (Kirkpatrick et al., 2006; Laughren and Levin, 2006). The first goal was to examine the scale's latent structure through a series of complementary structural analyses. Clarification of the underlying structure of the scale items, which were designed to comprehensively cover five consensus-based content domains, is critical for optimal assessment of the negative symptoms (Blanchard and Cohen, 2006; Blanchard et al., 2011). This was followed by a series of scale development analyses, including analyses of item- and scale-level characteristics, within- and between-site inter-rater agreement, and a preliminary analysis of discriminant and convergent validity. The over-arching goal was to refine the CAINS for use in the final scale development phase of the CANSAS project.

2. Methods and materials

2.1. Participants

Participants were 281 people with schizophrenia (n = 223) or schizoaffective disorder (n = 58), ages 18–60, recruited from outpatient clinics at the four CANSAS sites (UCLA, UC-Berkeley, University of Pennsylvania, and the University of Maryland). Patients met diagnostic criteria based on the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID; First et al., 1996). Exclusion criteria were: episode of major depression or mania within the last month; substance dependence in the last six months; substance abuse in the last month; IQ < 70; history of head injury or neurological disorder; insufficient English fluency. All participants provided written informed consent before the study.

2.2. Procedures

A two-day training workshop preceded study initiation. Training included manual review, didactic presentations, independent ratings of videotaped CAINS and other scales interviews, and discussions. Raters were credentialed for all study instruments following practice and confirmation of competency for videotaped and in-person interviews. Procedures were identical at all sites and approved by their institutional review boards. A detailed manual for training and supervision was developed and revised throughout the course of the study.

Following revisions from the feasibility study (Forbes et al., 2010), the CAINS-beta 2 included 23 items covering (1) asociality (3 items covering family, romantic relationships, and friendships), (2) avolition (4 items covering social interactions, vocational activities, recreational activities, and self care), (3) anhedonia (9 items, covering frequency, intensity, and expected pleasure in social, physical, and recreational activities), (4) blunted affect (5 items covering facial, vocal, gestural expression as well as eye contact and spontaneous movement) and (5) alogia (2) items covering quantity of speech and spontaneous elaboration). As discussed elsewhere (Blanchard et al., 2011), the first three domains are assessed based on patients' reports of motivation, interest, and emotional experience, as well patients' reports of actual engagement in relevant social, vocational, and recreational activities. The items in these areas do not exclusively focus on level of functional attainment because poor functioning may reflect factors that are unrelated to negative symptoms (e.g., paranoia, anxiety, skill deficits, lack of opportunity). Thus, the items were designed to more closely measure constructs that are central to negative symptoms (i.e., deficits in interest, motivation, affiliative desire).

The final two domains are based on behavioral observations during the interview. We opted to be over-inclusive with respect to the number of items, recognizing that our systematic data analytic approach to scale development would result in a smaller yet psychometrically sound instrument. All items were rated on a 0 to 4 scale with higher scores reflecting greater psychopathology. The time period covered by the interview was the past seven days. Expected pleasure assessed future pleasure with no specified time period.

Three additional measures were included to characterize the sample and for use in preliminary convergent/discriminant validity analyses: the *Brief Psychiatric Rating Scale* (BPRS; Overall and Gorham, 1962), 24-item version, assessing *Positive*, *Negative*, *Depression-Anxiety*, and *Agitation* (Kopelowicz et al., 2008); the *Calgary Depression Scale for Schizophrenia* (CDSS; Addington et al., 1996; Addington et al., 1990), evaluating depressive symptoms; the *Wechsler Test of Adult Reading* (WTAR; Wechsler, 2001), providing a reliable estimate of full-scale IQ.

The CAINS, BPRS, CDSS, and WTAR were administered in a fixed order. CAINS assessments were videotaped for supervision and evaluation of inter-rater agreement. A random subset of 10 CAINS videos from each site was independently rated by two different raters at each of the four sites to evaluate both within-site and between-site agreements on a common set of 40 interviews.

2.3. Data analysis

Complementary classical test theory (CTT) and item response theory (IRT; Embretson and Reise, 2000; Reise et al., 2005) analyses evaluated the latent structure of the scale, item response characteristics, inter-rater agreement, and preliminary convergent and discriminant validity. Although CAINS items were written to over-inclusively sample from five consensus-based negative symptoms domains, it was not our intention to adhere to an a priori factor structure. Instead, decisions about the ultimate structure and content of the scale were based on converging structural analyses of the overall scale and multiple item-level analyses.

We adopted several guiding principles for making data-driven decisions about retaining, modifying, or deleting items. Items that failed to meet one of these criteria were considered for deletion: (1) item fit with the factor structure of the scale, (2) inter-rater agreement within- and between-sites, (3) minimal redundancy with other items, (4) item-total correlations, (5) item skew, and (6) convergent and discriminant validity.

Data analyses thus included multiple procedures. The latent structure of the scale was evaluated using four complementary approaches. Our primary analytic approach was exploratory factor analysis using principle axis extraction with promax rotation. Complementary structural analyses were conducted to confirm the replication of this initial structure including cluster analysis (Aldenderfer and Blashfield, 1985), Bass-Ackwards analysis (Goldberg, 2002), and Mokken Scaling analyses (Sijtma and Molenarr, 2002). Following confirmation of the CAINS general structure, additional analyses to evaluate performance of constituent items included: (a) item-level descriptive statistics, including skewness and item-total correlations; (b) inter-rater agreement with Intraclass Correlation Coefficients (ICC's; model: two-way mixed; type: absolute agreement) at both within- and between-site; (c) correlational analyses to assess whether the CAINS subscales significantly correlated with the BPRS negative symptom subscale to assess convergent validity. Discriminant validity was assessed by examining correlations between the CAINS subscales and measures of positive and affective symptoms, which were expected to be small; (d) item response theory (IRT) analyses to assess whether each of the five within-item response options was functioning adequately, and to guide item revisions and further item deletions.