

The Creation and Validation of the Jamaica Personality Disorder Inventory

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ABSTRACT

Objective: To describe the creation and validation of the Jamaica Personality Disorder Inventory (JPDI) screening questionnaire.

Method: Using the phenomenological triad of power management, dependency and psychosexual issues, drafts of the JPDI were piloted on patients from psychiatric and medical wards. The JPDI consisted of 38 close-ended, yes/no questions. Validation was conducted in a sample of 200 patients, using the International Personality Disorder Examination–Screening Instrument (IPDE-S), the Brief Screen for Depression and consultant psychiatrists' Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) personality disorder interview. Construct validity was assessed through principal component factor analysis; Spearman correlation was used to assess criterion-related and discriminant validity; Cronbach's alpha was used to assess reliability of the entire scale as well as the resulting factors. The Multitrait Multimethod Matrix (MTMM) was used to assess discriminant and construct validity.

Results: Factor analysis revealed eight clusters consisting of 30 of the 38 questions, which had close congruence with the clinical triad. Cronbach's alpha for the entire scale was $\alpha = 0.79$, ranging from a high 0.70 to 0.82 to low 0.63 to 0.45. The JPDI exhibited a sensitivity of 95.06% and a specificity of 67.71%. Significant correlation of scores for the JPDI and IPDE-S ($r = 0.432$, $p = 0.000$) and the JPDI and the DSM IV-TR diagnosis ($r = 0.598$, $p = 0.000$) established concurrent validity for the JPDI. Correlations ($r = 0.293$, $p = 0.000$) suggested that the JPDI possessed predictive validity. The complete sample matrix of the MTMM provided evidence of both convergent and discriminant validity, and thereby, construct validity.

Conclusion: The JPDI demonstrated reliability, and criterion-related and discriminant validity.

Keywords: Inventory creation, inventory validation, Jamaica Personality Disorder Inventory (JPDI), personality disorder

Creación y Validación del Inventario de Trastornos de la Personalidad en Jamaica

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RESUMEN

Objetivo: Describir la creación y validación del cuestionario de tamizaje del Inventario de Trastornos de la Personalidad en Jamaica (JPDI).

Método: Usando la tríada fenomenológica de manejo del poder, dependencia y problemas psicosexuales, se realizaron pruebas pilotos usando versiones provisionales del JPDI con pacientes de salas médicas y psiquiátricas. El JPDI constaba de 38 preguntas cerradas, del tipo que requieren sí o no. La validación se realizó con una muestra de 200 pacientes, usando el Instrumento de Tamizaje del Examen Internacional de los Trastornos de Personalidad (IPDE-S), la Prueba Breve para la Depresión, y el Manual Diagnóstico y Estadístico de los Trastornos Mentales, cuarta edición (DSM-IV) de los psiquiatras consultantes, para entrevistas de trastornos de personalidad. La validez de constructo se evaluó a través de análisis factorial de componentes principales. El coeficiente de correlación de Spearman se utilizó para evaluar la validez de criterio y la validez discriminante. El coeficiente Alfa

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de Cronbach fue utilizado para evaluar la fiabilidad de toda la escala, así como los factores resultantes. La matriz multirasgo-multimétodo (MTMM) fue utilizada para evaluar la validez de constructo y la validez discriminante.

Resultados: El análisis factorial reveló ocho clústeres que constaban de 30 de las 38 preguntas, las cuales presentaban una estrecha congruencia con la triada clínica. El Alfa de Cronbach para toda la escala fue $\alpha = 0.79$, fluctuando desde valores altos de 0.70 a 0.82 hasta valores bajos de 0.63 a 0.45. El inventario JPDI mostró una sensibilidad de 95.06% y una especificidad de 67.71%. La correlación significativa de las puntuaciones para el JPDI y el IPDE-S ($r = 0.432, p = 0.000$) y el JPDI y el diagnóstico de DSM IV-TR ($r = 0.598, p = 0.000$) estableció una validez concurrente para el JPDI. Las correlaciones ($r = 0.293, p = 0.000$) sugirieron que el JPDI poseía validez predictiva. La matriz completa de la muestra de la MTMM proporcionó evidencia tanto de la validez discriminante como de la validez convergente, y por ende, de la validez de constructo.

Conclusión: El inventario JPDI demostró fiabilidad, así como validez de criterio y validez discriminante.

Palabras claves: Creación de inventario, validación de inventario, Inventario de Trastornos de la Personalidad en Jamaica (JPDI), trastorno de la personalidad

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INTRODUCTION

Long-standing debates have called for the need to redefine personality disorder and to develop scales that accurately measure the condition (1). The transition in the conceptualization of personality disorder has moved from categorical/cluster to dimensional, but these systems have not provided a concrete solution to the classificatory conundrum (2, 3). A plethora of instruments developed over the past two decades to assist with the diagnosis of personality disorder (4) has yet to firmly establish validity and proven acceptability (5).

The Jamaican experience of personality disorder was initially explored in a pilot study of 34 patients (6). The phenomenological features of the patients in this cohort were collated and aggregated which fell into three distinct clusters which were labelled 'power management issues', 'dependency issues' and 'psychosexual issues'. This 'clinical triad' of abnormal thoughts, feelings and actions was subsequently elaborated in a group of 351 patients (7). When disaggregated, the individual phenomenological features typically associated with personality disorder did not cluster into the traditional Diagnostic and Statistical Manual of Mental Disorders, fourth edition, text revision (DSM-IV-TR) categories, but were reconceptualized as a 'clinical triad'. Based on this, The University of the West Indies, Section of Psychiatry, Jamaica, established the Jamaica Personality Disorder Inventory (JPDI) in 2006. The objective of this study is to describe the creation and validation of this questionnaire designed to detect personality disorders specifically in Jamaica.

SUBJECTS AND METHOD

The research team created, analysed and formatted a survey instrument to test for personality disorder based on the three phenomenological factors identified in the Jamaican case-

control study (6). Focus group meetings identified phenomenological features of psychosexual problems, physiological and psychological dependency, while interpersonal conflicts and power struggles characterized power management problems. Focus groups developed questions that effectively captured the assigned constructs and the components of the concepts. The questions were revised from pilot tests done with approximately twenty lucid patients conveniently sampled from the psychiatric ward of the University Hospital of the West Indies (UHWI). The pilot testing culminated in the final interview schedule of thirty-eight close-ended, dichotomously rated (yes/no) questions.

Study participants

Subjects for the validation study were 200 Jamaican patients recruited from the psychiatric and medical wards of the UHWI in Kingston, Jamaica, between 2006 and 2008: 100 patients who were sequentially admitted to the psychiatric units of the hospital were matched for gender, age and social class (8) with 100 patients admitted to the general medical wards. Medical patients who had a previous psychiatric diagnosis were excluded from the study. There were no special attempts made to select patients who were known or suspected to have a diagnosis of personality disorder.

Measures

Jamaica Personality Disorder Inventory (JPDI): This is a 38-item interviewer administered questionnaire that was developed as a screening tool to identify the probability of being diagnosed with a personality disorder. Taking approximately 30 minutes for administration, it is intended to be linguistically simple and relevant to the reconceptualization of personality disorder (6, 7).

The International Personality Disorder Examination – Screening instrument (IPDE-S): The IPDE-S (1) is a self-

report measure of personality disorder. It is an abbreviated version of IPDE and has only 77 questions requiring true or false responses. The IPDE-S serves as the best approximation to a gold standard of a screening tool that can only detect the probable presence or absence of a personality disorder.

Brief Screen for Depression (BSD): This was included in this study to assess the discriminant validity of the JPDI and consists of four items, each of which assesses one set of depressive symptoms. The BSD has been shown to correlate strongly with other measures of depression and to have acceptable degrees of reliability. It was validated for use in a Jamaican cohort in 2007 (9).

DSM IV-TR semi-structured clinical interview: Using this clinical interview, one of three consultant psychiatrists sought to determine whether or not the patient met the DSM IV-TR criteria for a personality disorder. The consultant psychiatric interview garnered a diagnosis, psychosocial and phenomenological information about the patient.

Procedures

The first one hundred patients who were sequentially admitted to the psychiatric wards were identified. The JPDI, the IPDE and the BSD were administered. On the same day, one of three consultant psychiatrists, blind to the assessments, conducted the clinical interview. Patients from the medical wards who were eligible for participation based on their match by age, sex, socio-economic status and mental stability were then also similarly assessed.

Statistical analysis

Analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 16. Principal component factor analysis (PCA) with varimax rotation was used to determine whether the scale items clustered to represent the three domains of personality disorder conceived of as the 'clinical triad' (construct validity), whether these underlying constructs explained significant portions of the variance identified, and to examine the factor loadings in order to explain the meaning of each construct. Item loadings of at least 0.40 were considered to load significantly onto a particular factor. The internal consistency of the JPDI was measured by calculating the Cronbach's alpha (α) for the 38-item questionnaire after omitting each item and for the overall score. Reliability coefficients were also computed for each of the factors identified in the PCA. A *t*-test was employed to determine the cut score on the JPDI which correlated with the psychiatrist diagnosis of personality disorder. The performance of the JPDI at different cut scores was assessed by reference to the sensitivity, specificity and predictive values of the psychiatrist clinical interview. Correlations between the JPDI, the IPDE-S, the clinical diagnoses, and the location of patients were conducted to assess concurrent and predictive (criterion-related) validity, and against the BSD to examine discriminant validity of the JPDI.

The Multitrait Multimethod Matrix [MTMM] (10) is a matrix or table of correlations arranged to facilitate the interpretation of the assessment of construct validity, and compares the results of the two methods of assessment – in this study, the self-report questionnaires (the JPDI and the BSD) and the DSM IV-TR semi-structured clinical interview by the psychiatrist. The MTMM provides an operational methodology for assessing construct validity. In the single matrix, it is possible to examine both convergent and discriminant validity simultaneously.

RESULTS

A total of 200 patients were included in the sample of which most were male (61.0%), single (62.1%), and unemployed (62.5%). The average age of the patients was 37.1 years [SD 12.0, range 18–81] (Table 1).

Table 1: Demographic distribution of participants

	Psychiatric wards (n = 100)	Medical wards (n = 100)
Gender		
Male	61	61
Female	39	39
Age (years)		
Younger adults (18–39)	61	60
Mature adults (40+)	39	40
Social class		
I	6	6
II	3	3
III	5	5
IV	26	26
V	63	63

A factor analysis was conducted to examine the factor structure of 38 items of the JPDI. The suitability of the data for component analysis was tested *via* the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy and Bartlett's test of sphericity. The KMO measure in this study was 0.67, which indicates average values. Bartlett's test of sphericity ($\chi^2 = 1825.7$; $df = 666$; $p < 0.001$) verified that the matrix is not an identity matrix, that there are significant relationships between the items included in the analysis, and that the factor analysis is suitable. A total of 37 factors were identified, however, the scree plot suggested the most parsimonious result with eight factors denoting 52.3% of the variance were extracted and retained. Most of the variance was explained by the first factor (15.8%) with the other factors explaining between 8.1% and 3.7% of the variance. Eigenvalues for each of the eight factors ranged from 1.36 to 5.83, each accounting for 3.7% to 15.8% of the variance.

The item content of the eight factors was examined to formulate names based on hypothetical inferences about their relationships (Table 2). Of the 38-question items in the JPDI, a total of 30 were included in the eight factors identified, and questions 2, 7, 15, 25, 26, 28, 36 and 38 (Table 2) were omitted. Cronbach's alpha coefficient for the JPDI using the

Table 2: Pattern of factors after varimax rotation and Cronbach's alpha for the Jamaican sample

Item	Description	Pattern matrix								Scale if item removed
		1	2	3	4	5	6	7	8	
Factor 1: Physiological dependency										
(6 items; alpha = 0.81)										
5	In the past month have you used cigarettes?	0.786								0.79
4	In the past month have you used marijuana?	0.746								0.77
3	In the past month, have you used alcohol?	0.687								0.75
6	In the past month have you used cocaine?	0.640								0.78
23	Have you ever been imprisoned?	0.499								0.79
22	Have you ever been arrested?	0.462								0.77
Factor 2: Emotional dependency internalization										
(3 items; alpha = 0.82)										
17	If the person you depend on leaves you temporarily would you attempt suicide?		0.855							0.64
16	If the person you depend on leaves you temporarily do you injure yourself?		0.844							0.76
14	If the person you depend on leaves you temporarily do you destroy property?		0.771							0.82
Factor 3: Power management externalization										
(3 items; alpha = 0.70)										
19	Do you have quarrels almost every day?			0.842						0.45
18	Do you have disagreements almost every day?			0.809						0.55
20	Are you involved in physical fights?			0.453						0.79
Factor 4: Emotional dependency externalization										
(4 items; alpha = 0.58)										
12	If the person you depend on leaves you temporarily do you cry?				0.673					0.48
13	If the person you depend on leaves you temporarily do you have temper tantrums?				0.656					0.57
10	Do you depend on people for emotional support?				0.597					0.48
11	Do you depend on people for financial support?				0.504					0.49
Factor 5: Psychosexual problems internalization										
(4 items; alpha = 0.47)										
35	Do you have difficulty attaining an orgasm/ejaculation?					0.764				0.28
1	In the past month, have you used sleeping pills?					0.592				0.34
30	Have you ever had a homosexual/lesbian relationship?					0.547				0.46
37	Do you have guilt, pain or unpleasant feelings because of sex?					0.487				0.47
Factor 6: Psychosexual problems externalization										
(3 items; alpha = 0.62)										
34	Have you ever had more than one sexual partner in the past 12 months?						0.784			0.47
32	Do you have difficulty being sexually faithful to one person at a time?						0.754			0.44
33	Have you ever fantasized about sexual relationship with someone other than your partner?						0.405			0.66
Factor 7: Power management internalization										
(5 items; alpha = 0.63)										
9	Do you have a gambling problem?							0.636		0.62
22	Have you ever been arrested?							0.605		0.42
8	Do you have regular money management problems?							0.526		0.67
23	Have you ever been imprisoned?							0.494		0.50
31	Do you frequently think about having a homosexual/lesbian relationship?							-0.405		

Table 2 (cont'd): Pattern of factors after varimax rotation and Cronbach's alpha for the Jamaican sample

Item	Description	Pattern matrix								Scale if item removed	
		1	2	3	4	5	6	7	8		
Factor 8: Power management social extension											
(4 items; alpha = 0.45)											
29	Have you ever been evicted from rented premises?									0.691	0.32
24	Have you ever been fired or demoted from a job?									0.532	0.35
21	Do you take things that do not belong to you?									0.430	0.38
27	Do you pay your bills late?									0.450	0.47

entire sample was $\alpha = 0.79$, with scale item coefficients ranging from 0.77 to 0.80. All coefficients were higher than the recommended 0.70 indicating that the scale had suitable

reliability. Table 3 presents item analysis results and Cronbach's alpha coefficients that would be generated if each item were to be deleted from the instrument.

Table 3: Jamaica personality disorder inventory (JPDI) scale corrected item-total corrections (r_{i-t}) and alpha coefficients if items deleted (α_d)

JPDI items	Scale mean	r_{i-t}	(α_d)	
1	In the past month, have you used sleeping pills?	9.72	0.08	0.788
2	In the past month, have you used pain killers medication?	9.31	0.105	0.790
3	In the past month, have you used alcohol?	9.53	0.390	0.776
4	In the past month have you used marijuana?	9.60	0.439	0.774
5	In the past month have you used cigarettes?	9.54	0.535	0.769
6	In the past month have you used cocaine?	9.72	0.483	0.774
7	Have you been on regular prescription medication?	9.22	-0.037	0.796
8	Do you have regular money management problems?	9.36	0.402	0.776
9	Do you have a gambling problem?	9.77	0.213	0.784
10	Do you depend on people for emotional support?	9.59	0.287	0.781
11	Do you depend on people for financial support?	9.47	0.439	0.774
12	If the person you depend on leaves you temporarily do you cry?	9.66	0.165	0.786
13	If the person you depend on leaves you temporarily do you have temper tantrums?	9.71	0.300	0.781
14	If the person you depend on leaves you temporarily do you destroy property?	9.81	0.327	0.782
15	If the person you depend on leaves you temporarily do you behave violently towards others?	9.80	0.358	0.780
16	If the person you depend on leaves you temporarily do you injure yourself?	9.80	0.303	0.782
17	If the person you depend on leaves you temporarily would you attempt suicide?	9.79	0.375	0.780
18	Do you have disagreements almost every day?	9.67	0.366	0.778
19	Do you have quarrels almost every day?	9.77	0.406	0.778
20	Are you involved in physical fights?	9.74	0.374	0.778
21	Do you take things that do not belong to you?	9.75	0.523	0.774
22	Have you been arrested?	9.50	0.446	0.773
23	Have you ever been imprisoned?	9.66	0.420	0.776
24	Have you ever been fired or demoted from a job?	9.60	0.334	0.779
25	Have you ever been expelled/suspended from school?	9.66	0.434	0.775
26	Have you been expelled from church?	9.83	0.219	0.784
27	Do you pay your bills late?	9.44	0.037	0.793
28	Do you borrow money from people?	9.38	0.282	0.782
29	Have you ever been evicted from rented premises?	9.78	0.356	0.780
30	Have you ever had a homosexual/lesbian relationship?	9.84	0.171	0.785
31	Do you think about it frequently?	9.83	0.109	0.786
32	Do you have difficulty being sexually faithful to one person at a time?	9.60	0.134	0.788
33	Have you ever fantasized about sexual relationship with someone other than your partner?	9.20	0.181	0.786

Table 3 (cont'd): Jamaica personality disorder inventory (JPDI) scale corrected item-total correlations (r_{i-t}) and alpha coefficients if items deleted (α_d)

JPDI items	Scale mean	r_{i-t}	(α_d)
34 Have you ever had more than one sexual partner in the past 12 months?	9.54	0.199	0.785
35 Do you have difficulty attaining an orgasm/ ejaculation?	9.72	0.102	0.788
36 Have you ever had premature ejaculation?	9.59	0.290	0.781
37 Do you have guilt, pain or unpleasant feelings because of sex?	9.61	0.126	0.788
38 Do you think your behaviour is normal most of the time?	9.01	-0.292	0.800

An exploration of the data was conducted to determine the best score to divide participants into those who have a personality disorder *versus* those who do not. Clinical judgments of a consultant psychiatrist were used as the standard for establishing potential cut scores for the JPDI. Cut scores were chosen based on the balance between specificity and sensitivity such that sensitivity was given greater weight than specificity. This decision was based on the fact that the JPDI will be used as a screening instrument, and as such should have a greater sensitivity than specificity. Using values between the mean scores of 7.15 and 13.96, the sensitivity (95.06%) and specificity (67.71%) of the JPDI were found to be most acceptable when a cut-off score of nine was employed. The JPDI diagnosed a total of 118 persons in the sample as having a personality disorder. The psychiatrist concurred with the diagnosis of a personality disorder in 77 of these cases, 34.7% less than the JPDI. Where the JPDI diagnosed a total of 90 persons in the sample as not having a personality disorder, the psychiatrist concurred with the diagnosis for 86 of these persons. This indicates that the JPDI is likely to produce a higher false positive rate but very low false negative rate in comparison to psychiatrists' diagnosis.

An estimate of concurrent validity was obtained by correlating the JPDI with the IPDE-S. To estimate predictive validity, categorical scores on the JPDI (personality disorder *versus* no personality disorder) were cross-tabulated with the type of patient (psychiatric *versus* medical). The Spearman rank-order correlation of categorical scores for the JPDI and IPDE-S was $r = 0.432$ ($p = 0.000$). Table 4 displays the

Table 4: Bivariate analysis of the Jamaica personality disorder inventory (JPDI) and international personality disorder examination-screening instrument (IPDE-S)

IPDE-S	JPDI Personality disorder	
	Absent	Present
Personality disorder		
Absent	43 (97.7%)	1 (2.3%)
Present	72 (46.2%)	84 (53.8%)

$r = 0.432, p = 0.000$

cross-tabulation of JPDI and IPDE-S scores which shows that the JPDI had a high false negative rate (46.2%) combined with moderate true positive (53.8%) and true negative rates (97.7%). Correlation analysis between the JPDI and the psychiatric assessment of the presence/absence of a personality disorder was also significant ($r = 0.598; p = 0.000$). These results suggest that the JPDI may have an acceptable level of concurrent validity.

Significant Spearman rank-order correlation of categorical scores for the JPDI and location of patient was also found [$r = 0.293, p = 0.000$] (Table 5). As indicated by the

Table 5: Bivariate analysis of the Jamaica Personality Disorder Inventory (JPDI) by location of patient

Location of Patient	JPDI Personality disorder	
	Absent	Present
Medical ward	72 (72.0%)	28 (28.0%)
Psychiatric ward	43 (43.0%)	57 (57.0%)

$r = 0.293, p = 0.000$

cross-tabulation percentages, the JPDI was two times more likely to identify the presence of a personality disorder on a psychiatric ward (57.0%) than on a medical ward (28.0%).

The data (Table 6) meet the four principles for establishing the construct validity of a measure in an MTMM for Campbell and Fiske (11).

Table 6: Multitrait-multimethod matrix – complete sample

	JPDI	Consultant personality disorder	BSD	Consultant depression
JPDI	0.79			
Consultant personality disorder	0.60	0.89		
BSD	0.18	0.21	0.62	
Consultant depression	0.23	0.26	0.64	0.68

JPDI: Jamaica Personality Disorder Inventory, BSD: Brief Screen for Depression

The heterotrait-monomethod triangles comprise correlations among measures that share the same method of measurement. If discriminant validity is to be proven then the correlations among these measures must be low. The low values for the whole sample matrix of 0.18 and 0.26 for the BSD *versus* JPDI (same method – self report inventory; different trait – depression and personality disorder) and psychiatrist diagnosis of depression *versus* psychiatrist diagnosis of personality disorder (same method – clinical interview; different trait – depression and personality disorder) are among the lowest in the matrix. This is evidence of discriminant validity. There is a relatively high correlation, 0.60, between the JPDI and the psychiatrist's diagnosis of personality disorder, and is substantive grounds for establishing convergent validity. The complete sample matrix provides evidence of both convergent and discriminant validity and meets the criteria for construct validity.

DISCUSSION

The JPDI was developed to measure personality disorder reconceptualized as a unitary construct with the three underlying dimensions: psychosexual problems, dependency and power management issues (6). Principal components factor analysis identified eight factors based on the item clustering of the questions in the measure, accounting for half of the total variance in the scale. These subscales consisted of 30 of the total scale items, suggesting that the excluded eight questions be modified by more strongly representative questions. The majority of the JPDI questions (79%) are representative of the reconceptualized model of personality disorder. In general, the JPDI demonstrated robust evidence for its reliability as indicated by the internal consistency of the entire scale ($r = 0.79$). Although the factors contain items that are generally representative of the clinical triad, the first three factors met or exceeded the recommended reliability value of 0.70 for the development of a questionnaire (11), suggesting the need to strengthen the other measures of the underlying dimensions of personality disorder.

In the initial studies of personality disorder in Jamaica (6, 7), a greater frequency of ego-dystonic homosexuality was identified within the personality disordered patients in comparison to patients diagnosed with Axis I disorders. Ego-dystonic sexual orientation is recognized as a disorder of sexual development and orientation by the World Health Organization (WHO) in the International Classification of Diseases (ICD) 10, but is excluded in the DSM IV-TR classification system. It is in this context that the question of homosexuality is included in the JPDI.

Evaluation of the JPDI against other measures of personality disorder as well as a conceptually different measure (BSD) found significant concurrent validity in correlations between the JPDI and the IPDE-S and psychiatric assessments of the presence/absence of personality disorder. Predictive validity was also established as the JPDI was able to correctly forecast membership in a particular patient group

(based on ward location). Discriminant validity was also identified in the negative, weak correlations between the JPDI and the BSD – two conceptually different measures. Taken together, these results suggest that the JPDI may be a useful screening instrument for personality disorder based on the clinical triad formulation (6). The overall results suggest its reliability and validity as a screening instrument. It represents a useful tool in the armamentarium of the primary care physician as well as mental health practitioners for the first identification of patients likely to be diagnosed with a personality disorder. The JPDI is a linguistically simple and brief screening tool that is representative of the reconceptualized personality disorder and can be used in areas where there is limited access to psychiatric services. Its simplicity of use should also encourage further studies on personality disorder in the Jamaican population.

Limitations

- * Coding of consultants who carried out specific interviews was not done, thus inter-rater reliability in the administration of the instruments was not assessed.
- * The consultants' diagnosis of personality disorder was recorded dichotomously rather than continuously, limiting the types of analysis that could be conducted.
- * Informants were not used to verify if subjects had been truthful in their responses.
- * Acute psychosis was used as an exclusion criterion for selection of participants, based on clinical judgment only.
- * The use of medical patients as representative of the general population can be questioned.

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