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ORIGINAL RESEARCH PAIN MANAGEMENT

Development and validation of Redeemer's University Primary Dysmenorrhea Screening Tool (RUN-PDST)

Ibukunoluwa Busayo Bello [1], Ebenezer Akinnawo Olutope [2], Bede Chinonye Akpunne [3]

Authors Affiliations:

1. Ibukunoluwa Busayo Bello, Department of Psychology, Faculty of Social Sciences, Redeemer's University, Ede, Osun State, Nigeria; E-mail: belloi1@run.edu.ng
2. Ebenezer Akinnawo Olutope, Department of Pure and Applied Psychology, Faculty of Social Sciences, Adekunle Ajasin University, Akungba, Ondo State, Nigeria; E-mail: topewutoji@yahoo.com
3. Bede Akpunne Chinonye, Department of Psychology, Faculty of Social Sciences, Redeemer's University, Ede, Osun State, Nigeria; E-mail: akpunneb@run.edu.ng

Correspondence: Ibukunoluwa Busayo Bello; **E-mail:** belloi1@run.edu.ng

ABSTRACT

Background: Primary dysmenorrhea is often overlooked, underdiagnosed, and under-treated. This study attempts to develop a standardized tool for assessing primary dysmenorrhea among women in their reproductive years.

Methodology: This study utilized a mixed-method approach to sample young Nigerian women. Specifically, the development of the Redeemer's University Primary Dysmenorrhea Screening Tool (RUN-PDST) involved a standardized methodology comprising two broad phases: (a) development and refinement of screening tool items and (b) establishment of psychometric properties.

Results: The observed Kaiser-Meyer-Olkin (KMO) measure was .86, and Bartlett's Test of Sphericity (BTS) was (X^2=3518.512, df=703, P = .000). The test of the principal components indicated nine extracted components, and the analysis of the components revealed all items that loaded based on the presence of nine components exceeding an eigenvalue of 1. Of the 38 items loaded, 24 were found to be significant and were subjected to principal component analysis using Varimax. The results from the component analysis further reduced the screening tool to 19 items. The item-total statistics of the tool indicate that all items have very good discrimination ability and should be retained. The internal consistency of the RUN-PDST among Nigerian samples revealed that the screening tool is reliable. Furthermore, paired with The Menstrual Symptom Questionnaire (MSQ), RUN-PDST has good concurrent validity.

Conclusion: RUN-PDST is a reliable and valid screening tool for assessing and managing primary dysmenorrhea symptoms.

Abbreviations: RUN-PDST – Redeemer's University Primary Dysmenorrhea Screening Tool; PCA - Principal Component Analysis; BTS - Bartlett's Test of Sphericity; KMO - Kaiser-Meyer-Olkin; MSQ - Menstrual Symptom Questionnaire

Keywords: Development, validation, primary dysmenorrhea, screening tool.

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1. INTRODUCTION

In many societies, menarche - the onset of menstruation – is not merely a biological event but a significant milestone that marks the hallmark of puberty and entry into womanhood, with implications for social identities and roles.[1] Upon this transition, a girl, now termed a 'woman', will, on average, have a menstrual cycle length of between 4 – 11 days from the onset of menarche under 20 years old to the onset of menopause at above 50

years.[2] While the onset of menstruation is usually greeted with celebrations and increased formal and informal education regarding pregnancy and sexually transmitted diseases, menarche (or a few years into regular menstruation) may also herald the onset of new experiences of pain for many women.[3]

Williams and Craig[4] defined pain as "a distressing experience associated with actual or potential tissue damage with sensory, emotional, cognitive and social components." According to the American College of Obstetricians and Gynecologists,[6] over 50 per cent of women who menstruate will experience some pain associated with menstruation, also known as dysmenorrhea, for 1 to 2 days each month. Dysmenorrhea, which is typically operationalized as pain in the lower abdominal region occurring shortly before or during mensturation,[6] and may be accompanied by other premenstrual and menstrual physical and emotional symptoms such as thigh pain, back pain, gastrointestinal symptoms (such as bloating, nausea, vomiting, and diarrhea), tender breasts, headaches, fatigue, lack of concentration, and mood swings.[7,8]

Evidence suggests that dysmenorrhea is the most prevalent cause of gynecological morbidity in women of reproductive age,[9,10] and has a significant impact on life course potential,[9] short-term absenteeism from school and work, and it may pose a risk for the development of other chronic pain illnesses.

It has also been identified as the leading cause of short-term absenteeism from school and work among women of reproductive age and is a risk factor for other chronic pain illnesses.[11,12]

There are two broad classifications of dysmenorrhea: primary and secondary dysmenorrhea[5]. Primary dysmenorrhea refers to painful menstruation in women with normal pelvic anatomy, caused by prostaglandins that are made in the lining of the uterus, which cause muscle and blood vessel contractions, thereby resulting in pain, which usually presents as cyclic pain starts within a few hours of the onset of menses and usually resolves within 72 hours.[5,13,14] Conversely, in secondary dysmenorrhea, pain tends to get worse as the period continues and may not go away after it ends.[5] It is associated with gynecological morbidities and is often attributed to underlying organic diseases such as adenomyosis, endometriosis, and uterine myomas.[13]

Primary dysmenorrhea classically begins within about two years of menarche or once ovulatory cycles have been established and is more often a diagnosis made in adolescents and young adults.[14] Studies reveal that the worldwide prevalence of primary dysmenorrhea ranges from 45 to 95% of women of reproductive age, where 2–29% experience severe pain.[15] Also, like many other countries across the globe, Nigeria has a high prevalence – 77.8% - of primary dysmenorrhea.[16] Although outcome measures of primary dysmenorrhea exist[17], indigenous and culture-specific primary dysmenorrhea screening tools are limited for Nigerian clime and related environs. Therefore, this study seeks to develop the Redeemer's University Primary Dysmenorrhea Screening Tool (RUN-PDST) as an indigenous and culture-sensitive measure of primary dysmenorrhea.

2. METHODOLOGY

This study utilized a mixed-method design to develop and validate the screening tool. A standardized methodology comprising two broad phases, (a) development and refinement of screening tool items and (b) establishment of psychometric properties, was utilized.

The working hypothesis of this study is that Redeemer's University Primary Dysmenorrhea Screening Tool is a valid and reliable tool for assessing primary dysmenorrhea symptoms among women in their reproductive years. This study was conducted by sampling female undergraduates in Osun State, Nigeria. The sample consisted of unmarried female undergraduates in good physical condition (self-reported) willing to spend about 5 minutes on the study. Non-menstruating female students and female students who reported a history of pelvic pathology or hysterectomy were excluded from this study.

The first phase of data collection from 155 undergraduates of Redeemer's University, using a simple random sampling technique, was conducted using a survey in November 2020. In contrast, the second data collection phase from 454 Osun State University undergraduates, using a simple random sampling technique, occurred in May 2021.

The total population of undergraduates in the selected universities is more than 10,000. For Phase Two of this study, the sample size determination formula for a population of more than 10,000 was used to obtain the final sample estimate (n).[18]

The formula population of more than 10,000 is given as:

$$n = \frac{(Z_{\alpha/2})^2 * P\,(1 - P)}{d^2}$$

Where,

n = sample size

p = proportion in the target population estimated to have a particular characteristic

z = standard normal deviate, usually set at 1.96, which corresponds to the 95% confidence level

d = degree of accuracy desired, usually set at 0.05, 0.03, or occasionally at 0.02.

The following criteria were used to determine the sample size: Based on a pilot study conducted with 212 participants, there was a 58.5% prevalence of primary dysmenorrhea among the participants. Therefore p = 0.59

1. A confidence level of 95% was used
2. The degree of precision (Margin of error) was set at 5.0%

$$n = (1.96)^2 * 0.59 (1 - 0.59)$$
$$(0.05)^2$$
$$n = 371.71$$

Research ethics for human subjects were observed in compliance with the Helsinki Declaration. The authors obtained participants' consent before the administration of the screening tool. However, ethical codes do not apply to this research type (See National Code of Health Research Ethics; National Health Research Ethics Committee of Nigeria (NHREC) – Section B, Item A).

Statistical Package for Social Sciences (SPSS) version 21 was used to analyze the results obtained from the three phases of the study. The tests conducted included Principal Component Analysis (PCA), Bartlett's Test of Sphericity (BTS), KMO, scree plots, varimax analysis, item-total statistics, correlation matrix, reliability coefficients, cut-off point estimation using 95% confidence interval, and determination of scoring pattern for the screening tool.

3. RESULTS

3.1. Phase One: Development and Refinement of RUN-PDST items

In the first stage of development, the screening tool involved 38 items comprising physical, psychological, gastrointestinal, and cognitive symptoms guided by prevailing clinical features, literature, and test-development ethics. The initial 38 items generated for the RUN-PDST were administered to 155 female university undergraduates to generate data for exploratory factor analysis (EFA). Participants were aged between 15 and 28 years (mean = 19.39; SD=2.12), while age at menarche ranged between 8 and 20 years (mean = 11.99; SD=2.72). The mean menstrual cycle duration among the participants was 25.61 days, while the mean number of days of menstrual flow was 4.65.

An EFA was performed to uncover the underlying structure and relationship of primary dysmenorrhea components. These multivariate statistics provided the Principal Components Analysis (PCA), Bartlett's Test of Sphericity (BTS)[19] and the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy[20] of the 38 items of the RUN-PDST.

KMO and Bartlett's tests were conducted to identify the factorability of the screening tool. The results reveal a KMO measure of sampling adequacy of .86, which falls within the statistically significant range of 0 to 1. Bartlett's test of sphericity was also significant (X^2=3518.512, df=703, p = .000), and these results confirm the factorability of the correlation matrix. Hence, the Principal Components Analysis (PCA) was conducted. Therefore, the factor analysis was considered appropriate. The principal component extraction method test indicated nine extracted components, and the study of the components revealed all items loaded based on the presence of 9 components exceeding an eigenvalue of 1. The Eigenvalues of the nine components ranged between 12.296 to 1.048, with a percentage ranging from 32.358 to 2.758.

A scree plot was used to corroborate the EFA of the components to retain the RUN-PDST. The scree plot confirmed a break after the third component, corroborating the PCA findings. Further investigation is required based on the PCA load of the nine components, with a cumulative percentage of 32.358.

The loadings of the 38 items under the nine components are presented in Table 1.

Table 1 indicates that 29 of the 38 items loaded best in the first component, 2 in the second component, 2 in the fifth component, 2 in the sixth component, and 1 in the seventh component.

Seven of the 29 items in the first component were also loaded into the other components, rendering them complex structures and deleted. Other complex structures included one item in the second component and two in the fifth component. All the complex structures were deleted.

Fourteen items were loaded in more than one component of all loaded components, rendering these items as complex structures. The identified complex structures and the items loaded on the fifth, sixth and seventh components were deleted from the scale, after which the remaining factors were subjected to a varimax analysis.

Table 2 indicates that 21 of the 24 items loaded best in the first component, one in the second component, one in the fifth component, and one in the sixth component.

Two of the 21 items in the first component were loaded in more than one component, rendering those items complex structures. The item in the second component is loaded in more than one component, rendering the item a complex structure. The loaded in the fifth component was loaded into more than one component, rendering the item a complex structure.

Four items are loaded in more than one component of all loaded components, rendering those items as complex structures. The identified complex structures and items loaded on the sixth component were removed from the scale. Based on these, 19 items were retained. The 19 items that were retained are tabulated below.

Component Matrix

	Component									
	N	1	2	3	4	5	6	7	8	9
Difficulty concentrating	PDST 31	.738								
Disorientation	PDST 38	.734								
Difficulty remembering newly learned lists, names, and other verbally told information	PDST 32	.727								
Difficulty performing newly learned complex tasks	PDST 34	.713								
Difficulty remembering old memories	PDST 33	.708		-.401						
Inability to perform day-to-day tasks without assistance	PDST 37	.675								
Trouble organizing and planning	PDST 35	.671								
Anger	PDST 22	.665								
Rapid, strong or irregular heartbeats	PDST 24	.651								
Impaired reading comprehension	PDST 36	.649								
Loss of self-confidence	PDST 30	.649								
Anxiety	PDST 23	.648								
Disrupted sleep	PDST 29	.641								
Loss of interest in previously pleasurable social activities	PDST 27	.630								
Loss of interest in previously pleasurable home activities	PDST 26	.617	-.423							
Dizziness	PDST 12	.613								
Bloating	PDST 16	.602						-.446		
Fatigue	PDST 11	.595								
Loss of interest in previously pleasurable school activities	PDST 25	.589	-.443							
Inability to sleep as comfortably as before	PDST 28	.581								
Low mood	PDST 21	.576		.495						
Headaches	PDST 10	.562	.456							
Diarrhea	PDST 18	.558								
Migraines	PDST 9	.556	.477							
Pain in the lower back	PDST 6	.551								
Constipation	PDST 17	.539								
Excessive sweating	PDST 20	.527								
Nausea	PDST 15	.505								
Breast fullness and tenderness	PDST 4	.439								
Increased frequency of urination	PDST 19	.429								
Increased appetite	PDST 13	.388								
Joint/muscle aches and pains	PDST 8		.520							
Pain in the thigh and legs	PDST 7	.405	.485							
Pain in the lower abdomen	PDST 5					.613				
Decreased appetite	PDST 14	.405				-.441				
Heavy menstrual periods	PDST 1						.607			
Blood clots during menstruation	PDST 2						.572			
Irregular menstruation	PDST 3							.571		
Percentage of Variance		32.36	7.53	5.44	4.83	4.14	4.10	3.50	2.82	2.76
Cumulative Percentage		32.36	39.88	45.32	50.15	54.29	58.39	61.89	64.72	67.47

Table 2: The Principal Components Analysis of the 24-item measure for RUN-PDST using Varimax

Component Matrix[a]

	Component					
	N	1	2	3	4	5
Difficulty concentrating	PDST 31	.764				
Disorientation	PDST 38	.761				
Difficulty performing newly learned complex tasks	PDST 34	.741				
Difficulty remembering newly learned lists, names, and other verbally told information	PDST 32	.739				
Inability to perform day-to-day tasks without assistance	PDST 37	.720				
Trouble organising and planning	PDST 35	.717				
Impaired reading comprehension	PDST 36	.683				
Anger	PDST 22	.671		.417		
Disrupted sleep	PDST 29	.668				
Loss of self-confidence	PDST 30	.653				
Anxiety	PDST 23	.648				
Rapid, strong or irregular heartbeats	PDST 24	.644				
Dizziness	PDST 12	.623				
Inability to sleep as comfortably as before	PDST 28	.600				
Fatigue	PDST 11	.596				
Loss of interest in previously pleasurable social activities	PDST 27	.589				
Constipation	PDST 17	.538				
Excessive sweating	PDST 20	.538				
Diarrhea	PDST 18	.534				
Nausea	PDST 15	.517				
Pain in the lower back	PDST 6	.517			.444	
Joint/muscle aches and pains	PDST 8		.408		.543	
Increased frequency of urination	PDST 19	.432				-.567
Breast fullness and tenderness	PDST 4					.511
Percentage of Variance		38.46	7.33	5.89	5.63	4.65
Cumulative Percentage		38.46	45.79	51.68	57.31	61.96

Table 3: Item – Total Statistics of RUN-PDST

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Difficulty concentrating	20.28	152.412	.720	.740	.917
Difficulty performing newly learned complex tasks	20.75	155.381	.697	.617	.918
Difficulty remembering newly learned lists, names, and other verbally told information.	20.69	154.657	.701	.636	.917
Disorientation	20.52	153.355	.730	.696	.917
Trouble organizing and planning	20.48	154.446	.678	.650	.918
Inability to perform day-to-day tasks without assistance	20.30	152.940	.680	.610	.918
Impaired reading comprehension	20.63	156.236	.647	.630	.919
Disrupted sleep	19.97	154.194	.630	.629	.919
Loss of self-confidence	20.66	157.317	.614	.523	.919
Anxiety	20.05	155.212	.570	.495	.920
Rapid, strong or irregular heartbeats	20.63	157.314	.601	.571	.919
Dizziness	20.01	156.844	.560	.541	.920
Inability to sleep as comfortably as before	19.81	155.841	.554	.568	.921
Fatigue	19.60	158.216	.540	.481	.921
Constipation	20.37	158.987	.493	.430	.922
Loss of interest in previously pleasurable social activities	19.70	157.914	.528	.433	.921
Excessive sweating	20.52	159.888	.497	.473	.922
Diarrhea	20.00	158.195	.492	.456	.922
Nausea	20.34	158.798	.473	.380	.922

3.2. Phase Two: Establishment of Psychometric Properties of RUN-PDST

Summary of Reliability Testing for RUN-PDST

The corrected item/total correlations were used to indicate discrimination of the items in the screening tool. All items had values ranging between .473 - .730, indicating that all items have very good discrimination and should be retained.

The internal consistency of the RUN-PDST among the Nigerian sample revealed a Cronbach coefficient (α) of .91, a Spearman-Brown coefficient of .86, and a Guttman Split-Half coefficient of .85, indicating that the screening tool is reliable.

3.3. Concurrent Validity for RUN-PDST

For this phase of the study, four hundred and fifty-four (454) female undergraduates selected from Osun State University, Osogbo, Osun State, were sampled using Redeemer's University Primary Dysmenorrhea Scale (RUN-PDST) and Menstrual Symptom Questionnaire (MSQ). The Menstrual Symptom Questionnaire is a 25-item scale developed by Chesney and Tasto[21] to measure primary dysmenorrhea. Items were developed as measures of Dalton's[22] classifications of spasmodic and congestive types of primary dysmenorrhea. The first 24 items enable respondents to indicate the degree to which they experience the spasmodic or congestive symptoms by selecting one of five response choices ranging from "Never" to "Always."

Table 4 summarizes Pearson's *r* of the RUN-PDST and MSQ scores. The results show that both scales have a positive significant validity coefficient (r=.300, *p =.000).* This result proved that the RUN-PDST is valid for screening symptoms of primary dysmenorrhea among Nigerian women.

Table 6: Redeemer's University Primary Dysmenorrhea Screening Tool (RUN-PDST) Screening Tool

Instructions: *This form measures experiences of pain during menstruation. It is not a test, so there are no right or wrong answers. Please answer all items as carefully and accurately as possible by ticking or filling in the most appropriate response. Please tick the column' Not-Applicable for symptoms that do not apply.'*

During my menstruation, I experience…	Mild	Moderate	Severe	Not-Applicable
Difficulty concentrating	1	2	3	0
Disorientation	1	2	3	0
Difficulty performing newly learned complex tasks	1	2	3	0
Difficulty remembering newly learned lists, names, and other verbally told information	1	2	3	0
Inability to perform day-to-day tasks without assistance	1	2	3	0
Trouble organizing and planning	1	2	3	0
Impaired reading comprehension	1	2	3	0
Disrupted sleep	1	2	3	0
Loss of self-confidence	1	2	3	0
Anxiety	1	2	3	0
Rapid, strong or irregular heartbeats	1	2	3	0
Dizziness	1	2	3	0
Inability to sleep as comfortably as before	1	2	3	0
Fatigue	1	2	3	0
Loss of interest in previously pleasurable social activities	1	2	3	0
Constipation	1	2	3	0
Excessive sweating	1	2	3	0
Diarrhea	1	2	3	0
Nausea	1	2	3	0

Table 4: Correlation Matrixes of RUN-PDST and MSQ

	R	P	Mean ± SD
RUN-PDST	.300**	.000	40.93 ± 15.71
MSQ			73.12 ± 10.46

Table 5: The 95% Confidence Interval of cut-off point determination for RUN-PDST

	Sample
Margin of Error	1.45
Sample size	454
Sample mean	40.93
Standard deviation	15.71
95% Confidence Interval	40.93 (95% CI 39.5 to 42.4)
Cut-off point	≥ 39.5

3.4. Calculation of Norms for the RUN-PDST

This study employed the 95% Confidence Interval method to estimate the cutoff point for RUN-PDST. As summarized in Table 5, with 95% confidence, the population mean was between 39.5 and 42.4, based on 454 samples [40.93 (95% CI 39.5 to 42.4)]. The lower interval limit (i.e., mean score minus one margin of error) of ≥ 39.5 is considered the cut-off point for the sample.

3.5. Redeemer's University Primary Dysmenorrhea Screening Tool (RUN-PDST): Final Draft

Below is a sample of the Redeemer's University Primary Dysmenorrhea Screening Tool (RUN-PDST).The total primary dysmenorrhea score was ascertained by summing the scores per item in Table 6.

4. DISCUSSION

Primary dysmenorrhea (PD) is a common, overlooked gynecologic disorder characterized by menstrual pain associated with several physical and psychological symptoms that interfere with daily activities. [23] Despite the high prevalence of primary dysmenorrhea[15], only a relatively few scales ascertain the degree of menstrual

pain using specific symptoms.[17] The need for cultural sensitivity in psychometric assessments has never been more critical[24], as proper symptom assessment is a crucial step towards effective symptom management.[25] RUN-PDST is a user-friendly, relatively brief, and practical tool for assessing primary dysmenorrhea among women in their reproductive years by assessing key symptoms. The RUN-PDST is an initial indigenous standardized screening tool for evaluating primary dysmenorrhea; hence, it is culture-sensitive and suited for the Nigerian setting and its environs.

Table 7: Scoring of Redeemer's University Primary Dysmenorrhea Screening Tool (RUN-

Rating	Scoring
Absence	0
Mild Primary Dysmenorrhea	1-19
Moderate Primary Dysmenorrhea	20 – 38
Severe Primary Dysmenorrhea	≥ 39

The Principal Component Analysis (PCA) findings revealed that the RUN-PDST has only one factor with 19 items. The item-total statistics ranged between .473 - .730, indicating that all items discriminate well. The screening tool is also statistically reliable, as revealed by a high Cronbach's Alpha coefficient of .91, a Spearman-Brown coefficient of .86, and a Guttman Split-Half coefficient of .85 reliability scores. The results on the concurrent validity of the RUN-PDST and MSQ show that a positive significant validity coefficient exists between both scales (r=.300, *p =.000)*. Additionally, ≥ 39.5 is considered the cut-off point for the sample and the scoring pattern of the screening tool was generated to distinguish the levels of primary dysmenorrhea severity.

5. LIMITATIONS

Based on the self-report nature of the RUN-PDST, self-report bias may occur in response to the screening tool items. This should be considered when interpreting findings from this study and responses from the scale post-administration.

Also, data for this study were collected only from undergraduate students of selected universities in Nigeria, leaving out other populations that may experience the same symptoms. Due to the limitations of this study, re-validation of the scale is required when using different samples.

Although an exclusion criterion was used to identify female students with secondary dysmenorrhea, it could be that some of the students who reported having primary dysmenorrhea have a pelvic pathology associated with secondary dysmenorrhea which is not diagnosed or they have never been on a gynecological exam and their physical condition is unknown.

Despite limitations, the development and validation of RUN-PDST have several implications for assessing and managing primary dysmenorrhea. The original and primary data collection using randomly selected female undergraduate students for the two phases of the study are among the strengths of this study. Also, this study adds to primary dysmenorrhea literature and outcome measures by providing a culture-sensitive screening tool using a Nigerian sample.

From a methodological perspective, additional studies are needed to explore RUN-PDST's reliability and validity in other settings and languages. Further exploration of this screening tool could include developing a short version for increased time sensitivity.

6. CONCLUSION

In conclusion, the prevalence of primary dysmenorrhea is high, and its consequences are extensive. Assessing the severity of pain experienced during an episode of primary dysmenorrhea, the leading cause of gynecological morbidity, is germane for providing findings that can impact proper management. Therefore, this study aimed to develop a primary dysmenorrhea screening tool suitable for Nigerian climes. Authors, thus, recommend RUN-PDST as a primary dysmenorrhea screening tool among women of reproductive age in Nigeria and other regions with similar sociocultural settings.

7. Data Availability

The data supporting this study's findings are available upon request from the corresponding author.

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10. Conflict of interest

All authors declare no conflict of interest.

11. Authors' contribution

BIB: Conceptualisation; Literature review and item development; Research methods; Data collection; Data management; Data analysis; Writing – original draft; Writing – review & editing.

AOE: Conceptualisation; Research methods; Writing – review & editing.

ABC: Data analysis; Writing – review & editing.

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