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DEVELOPMENT AND PSYCHOMETRIC VALIDATION OF A SCALE FOR MEASUREMENT OF TRAMADOL ABUSE

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ABSTRACT

There are indications that the practices or behaviour involving tramadol use have not been measured with valid and reliable tools in the past. A scale that can be used to identify tramadol abuse practices in both clinical and non-clinical settings would be useful for possible intervention efforts. The objective of this study was, therefore, to develop and validate a scale to measure tramadol abuse. The scale items were sourced from the literature and outcomes from focus group discussions (FGDs) with 16 long-term tramadol users who were screened with Q-cup urine drug test kit (Q-CUDTK). Six experts and 30 long-term tramadol users were engaged for content and face validations of the items respectively. For construct validation, 180 tramadol users participated. Exploratory factor analysis (EFA) was applied to identify the underlying factor structure of the scale and Cronbach's alpha was computed for the scale internal consistency. Two items failed to meet the I-CVI (item-content validity index) cut-off point (I-CVIs < 0.83) and were deleted leaving 18 items with the S-CVI (scale-validity index) of 0.93. Three more items were deleted for having factor loadings below 0.50 leaving 15 items. The EFA resulted in the extraction of three factors: frequency of use (7 items), intensity of use (5 items) and pattern of use (3 items) with the reliability coefficients of 0.95, 0.96 and 0.89 respectively. We named this scale 'Tram-BEHAV' because it can be used to identify tramadol abuse behaviour for possible intervention. It can also be used for the evaluation of tramadol abuse intervention programmes.

Keywords: Development, validation, scale, tramadol abuse

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INTRODUCTION

Tramadol is one of the pharmaceutical opioids indicated for moderate to moderately severe pains. The analgesic is considered safer for prescription than other opioids like codeine, morphine, and fentanyl due to its lower potential for addiction (Ojha & Bhatia, 2010). However, evidence have emerged in recent times indicating unprecedented explosion in tramadol abuse among young people (Bashirian, Barati, & Fathi, 2014; Bassiony et al., 2015; Roussin, Doazan-d'Ouince, Geniaux, & Halberer, 2015). This could be attributed to the adulteration of the product by non-licenced pharmaceutical companies to meet the sexual, work performance and some emotional needs of the youths (Adeyeye, 2018; Chikezie & Ebuenyi, 2019; Fuseini, Afizu, Yakubu, & Nachinab, 2019; Ibrahim et al., 2017; Orhero, 2018).

Tramadol abuse literary means the use of the analgesic contrary to the medical and legal guidelines, or the use of tramadol for purposes other than pain treatment. A retrospective review on tramadol abuse showed that between 2006 and 2012, global tramadol consumption rate increased by 42% from 290 tons to 424 tons (Ahmed, El-Dawy, Fawzy, Abdallah, & Elsaid, 2018). The International Narcotics Control Board (INCB) data in 2013 indicated that thirty-three countries reported illicit manufacture of tramadol and heavy non-medical use with attendant debilitating health consequences (Ahmed et al., 2018). In Nigeria, tramadol has been identified as the most abused substance second to cannabis (National Bureau of Statistics, 2018). Studies have found association between tramadol addiction and complicated health conditions like psychiatric disorder, seizure, serotonin syndrome, cardiovascular collapse, and respiratory depression (El-Hadidy & Helaly, 2015; Kaye, 2015; Sansone & Sansone, 2009; World Health Organization, 2014). Another study reported 48% death rate associated with tramadol abuse in Northern Ireland (Randall & Crane, 2014).

The importance of identifying abuse practices and purposes of specific drugs cannot be over-emphasized. This is because, drugs have their various practices and purposes of abuse, and identifying these, may guide the development and implementation of specific intervention strategies. Previous studies on tramadol abuse, however, did not use any validated instrument with psychometric properties (Elliason, 2018; Iorfa, Ifeagwazi, Effiong & Essien, 2019; Madukwe & Klein, 2019; Tafesh, 2013). This could be due to non-availability of a valid and reliable instrument to serve the purpose. The few available valid and reliable instruments were developed to measure prescription opioids' abuse generally. Such instruments include Prescription Opioid Misuse and Abuse Questionnaire (Coyne et al., 2018), Prescription Drug Use Questionnaire (Compton, Wu, Schieffer, Pham, & Naliboff, 2008), Prescription Opioid Misuse Index (Knisely, Wunsch, Cropsey & Campbell, 2008), Opioid Prescription Medication Motives Questionnaire (Jones, Spradlin, Robinson, & Tragesser, 2014), and Addiction Behaviour Checklist (Wu et al., 2006). None of these instruments had measured tramadol abuse specifically and were clinical based only. Besides, all the five instruments were developed in America and of course, reflected Americans' orientation about prescription opioids. Therefore, administering these self-report instruments (without the mention

of tramadol) in developing nations of Africa where the level of education is low might not yield reliable responses as some users of tramadol may not consider it as a prescription opioid. We, therefore, developed and validated a scale to fill-up these important existing gaps in the measurement of tramadol abuse.

METHODS

A mixed-method design combining a qualitative study with quantitative procedures was applied. The development of the scale involved two stages. The first stage involves item generation and scale development while the second stage involves validation of the scale.

First Stage: Item Generation and Scale Development

The development of this scale followed the guidelines for development of questionnaires by Yaddanapudi and Yaddanapudi (2019) which include review of the relevant literature, discussion with experts/target group, generation of items, validation of items (face, content, and construct) and test of reliability. In compliance with the guidelines, the development of this scale started with literature search by accessing databases (PsycINFO, PubMed, google-scholar, Drug Database, Scopus, MEDLINE, Web of science and sociological Abstracts). The search terms included clinical use of tramadol, forms of tramadol, recommended dose for tramadol, tramadol abuse/misuse, non-medical purposes for tramadol use, and non-medical routes for tramadol administration.

After the literature search, a qualitative study was conducted among 16 long-term tramadol users in Buruku and Gboko Local Government Areas of Benue State to generate items for the scale. The participants were recruited through snowball sampling (Lewis-Beck, Bryman, & Liao, 2003), and were screened and confirmed to be tramadol users by using a urine multi-drug testing kit known as Q-cup urine drug test kit (Q-CUDTK) with 99% reliability (Wondfo Biotech, 2018). Focus group discussion (FGD) was the method of data collection while focus group discussion guide (which was developed and validated) was used as instrument for data collection. Two sessions of FGD were conducted: first one with eight participants in Buruku and the second one with the other eight participants in Gboko using a digital voice recorder. The two sessions were conducted to see if there would be varied responses to the FGD questions in different locations. Some of the questions covered by the FGD include "How do you get tramadol?" "What purpose (s) do you use tramadol for?" "What route (s) of administration do you use?" "How often do you use tramadol in a day?" "How much milligrams do you use in a day?". Data were analysed by thematic analysis (Castleberry & Nolen, 2018) using a computer-aided qualitative data analysis (CAQDA) software known as NVIVO version 10. Codes (responses) from the analysis were used to generate items and develop the scale.

Second Stage: Scale Validation

The scale was validated using content, face and construct validation methods as well as reliability.

Content Validation

Draft copies of the scale were emailed to six experts including two psychiatrists, two addiction counsellors, one psychologist and one expert in test and

measurement to rate the relevance and suitability of the items in the measurement of the behavioural traits or practices relating to tramadol use. A 4-point Likert scale with values ranging from 1 (item is not relevant) to 4 (item is highly relevant) was used. The experts were also requested to make qualitative judgement of the items. The rating scores of 1 and 2 were converted to '0' indicating invalid score while scores of 3 and 4 were converted to '1' indicating valid score (Yusoff, 2019a). These scores were entered into Microsoft excel to compute the item-level content validity index (I-CVI) and the scale-level content validity index (S-CVI) of the scale. The cut-off point for retaining items was set at 0.83 (Polit, Beck, & Owen, 2007).

Face Validation

The draft copies of the scale were given to 30 long-term tramadol users in Makurdi Local Government Area of Benue State, Nigeria who were indentified through snowball method to rate the clarity and the comprehensiveness of the items. This was done to ensure that the items were clear and understandable to the target population. They were requested to rate the degree of clarity and comprehensiveness of each item using a 4-point Likert scale ranging from 1 (item is not clear and understandable) to 4 (item is very clear and understandable). The rating scores of 1 and 2 were converted to '0' indicating invalid score while the rating scores 3 and 4 were converted to '1' indicating valid score (Yusoff, 2019b). The scores were entered into Microsoft excel to compute the item-level face validity index (I-FVI) and the scale-level face validity index (S-FVI). The cut-off point was set at 0.83 for retaining items.

Construct Validation

The methodology under this phase of validation is described under the subheadings of sample and sampling, research tool, data collection, data analysis and ethical approval.

Sample and Sampling

A sample of 180 youths in Logo and Tarka Local Government Areas of Benue State, Nigeria who were in the age bracket of 18 to 35 years were recruited to participate in the study. The choice of 180 participants as sample size was based on the rule of thumb recommendation of 'participants to item ratio' ranging from 3:1 to 20:1 for exploratory factor analysis (Costello & Osborne, 2005). For this validation study, a ratio of 10 participants per item was used to arrive at 180 participants (10 x 18 = 180) as two items were earlier removed from the initial 20 items for failing to meet the I-CVI cut-off point leaving an 18-item scale at this level. The snowball method of sampling was applied considering its effectiveness in the study of sensitive or private matters (Waters, 2015). The first few subjects that were identified through an informant were used in recruiting their fellow tramadol users after convincing them by explaining the purpose of the study and assuring them of confidentiality.

Research Tool

The scale consisting of six items on the demographic characteristics of the participants and 18 items on tramadol use was used for data collection. The response options were 'Very Untrue of me (VU), Untrue of me (U), Neutral (N), True of me (T) and Very True of me (VT)' with the numerical values of 1, 2, 3, 4 and 5 respectively. The scores of 1 and 2 indicate absence of the

behaviour or practice relating to tramadol use which is being measured by an item while scores of 3, 4 and 5 indicate presence of the behaviour or practice in question.

Data Collection

The data for this study were collected from April 2020 to May 2020 using face to face method of administration in the communities where the subjects were recruited. The maximum cooperation from the participants enabled successful retrieval of all copies of the scale with no loss recorded.

Data Analysis

Exploratory factor analysis (EFA) was applied using IBM Statistical Package for Social Sciences (SPSS) software version 26.0 to identify the underlying constructs of the scale. Descriptive statistics were first conducted to check for missing data and to confirm if the full range of 1 to 5 response options were chosen by the respondents. The Kaiser-Meyer- Olkin (KMO) Measure of Sampling Adequacy and the Bartlett's Test of Sphericity were checked to assess the suitability of the data for EFA. Data were considered factorable if the KMO index was greater than 0.50 and Bartlett's Test of Sphericity was significant ($P < .05$) (Williams, Onsman, & Brown, 2010).

The principal axis factoring (PAF) extraction method with Promax rotation was applied to maximize high item loadings and minimize low item loadings. Items were treated as continuous responses to allow evaluation of the dimensionality (number of factors). To determine the number of extracted factors, parallel analysis based on Eigen values > 1.0, and a scree plot inspection were performed. Factor loading cut-off point was set at 0.5 (Tabachnick & Fidell, 2013) and items with loadings < 0.5 were suppressed to prevent them from reflecting in the pattern matrix. For internal consistency (reliability) of the scale, Cronbach's alpha was computed and a reliability coefficient of > 0.7 was set as acceptable reliability (Taber, 2018).

Ethical Considerations

The study protocol was reviewed and approved by the Human Research Ethics Committee of Universiti Sains Malaysia (USM/JEPeM/19050316). Informed consent was also obtained from each participant who agreed to participate in the study after adequate briefing about the study.

RESULTS

Description of the Participants

Scale Development

The combined themes (non-prescription use of tramadol, use of tramadol for non-medical purposes, use of non-medical routes of administration, frequent and excessive use of tramadol) from literature review and FGD were used to generate an initial 20-item scale (Table 2). A section on demographic variables with six items was also created bringing the total number of the items to 26. The scale was developed in a self-report format, and a 5-point Likert scale response format of 'Very Untrue of me (VU), Untrue of me (U), Neutral (N), True of me (T) and Very True of me (VT)' with corresponding numerical values of 1, 2, 3, 4 and 5 (Viagas, 2006) was adopted for the scale. This response format was deemed appropriate for this scale as it seeks response on a behaviour or practice that reflects what a respondent does.

Table 1. Demographic Characteristics of the Participants (n = 180)

Variables	Mean (SD)	n	(%)
Age	26. 7 (4.7)		
Gender			
Male		168	(93.3)
Female		12	(6.7)
Marital Status			
Single		70	(38.9)
Married		105	(58.3)
Separated		4	(2.2)
Widowed		1	(0.6)
Level of Education			
Nil/Primary		6	(3.3)
Secondary		154	(85.6)
Tertiary		20	(11.1)
Occupation			
Farming		142	(78.9)
Trade		35	(19.4)
Civil Service		3	(1.7)
Duration of Tramadol Use			
< 1 Year		26	(14.4)
1 Year		5	(2.8)
>1 Year		149	(82.8)

SD = standard deviation, n = frequency

Content validity of the scale

The result of the content validation indicated that two items (Q11 and Q15) of the 20 items had item-level content validity index of less than 0.83 and were deleted, leaving 18 items. The S-CVI was 0.93, indicating excellent content validity for the scale. The suggestions by the experts to improve the quality of items and the actions taken are presented in Table 3.

Face validity of the scale

The result of face validation showed that only Q7 was not clear and understandable (I-FVI = 0.50 < 0.83). However, following the expert suggestion of keeping the item because of its' relevance in the measurement of tramadol abuse, an explanation was added to the item in bracket to read as "In the past two months, I have been snorting tramadol (inhaling tramadol through the nose)". The S-FVI of the scale was 0.97, indicating excellent face validity (S-FVI > 0.83).

Construct Validity of the scale

The Kaiser-Meyer- Olkin (KMO) Measure of Sampling Adequacy was 0.877 (> 0.50) and the Bartlett's Test of Sphericity was significant (P < .001) meaning data was factorable with EFA (Williams et al., 2010). The parallel analysis based on Eigenvalues > 1.0 with a variance cumulative percentage of 82.8 and a scree plot indicated extraction of three factors. The communalities were 0.435 to 0.975 for

Table 2. FGD Questions and Item Generation for the Scale

FGD questions	Responses	Application in the scale
How do you get tramadol? By doctor's prescription or over the counter?	● I buy tramadol over the counter ● I have never been to the hospital to see a doctor, but I use tramadol ● Mostly I get tramadol from friends but sometimes I used to buy from medicine shops	● I do not consult a doctor before using tramadol ● I buy tramadol from medicine shops anytime I want
Tell us the purposes for which you use tramadol	● To enjoy long sexual intercourse ● To get energy to work hard ● To feel high ● To treat body pains ● To induce sleep ● To make me bold ● To relieve stress ● To calm me down when I am angry	● I take tramadol every time I have urge for sex ● I take tramadol every time I want to stay long at work ● I use tramadol not minding whether I have pains or not ● I take tramadol every time I got offended by someone ● I do not go to work if I do not have tramadol
What routes or methods of tramadol administration do you adopt?	● I mix the tablets with energy drinks and take ● I use water to take tablets and capsules ● I inject myself with tramadol ● Sometimes I lick tablets or capsules of tramadol for quick action ● I used to wrap tramadol in a paper and smoke like tobacco for quick result.	● I used to dissolve tramadol tablets in energy drinks before taking ● I smoke tramadol for quick action ● I inject tramadol myself
Please tell us how often you use tramadol in a day	● I used to take tramadol anytime I have urge ● I do not miss taking tramadol at least 3 times in a day ● I use tramadol each time I want to have sex	● I take tramadol as many times as I have urge for it ● I take tramadol every time I have urge for sex ● A day hardly passes without me using tramadol
Tell us the maximum milligrams of tramadol you do consume in a day.	● I take 800mg of tramadol in a day. ● When we are competing, I take up to 1200mg in a day ● If I miss taking tramadol, I take more of it next time to cover-up.	● I consume more than 400mg of tramadol everyday ● I compete with friends for highest consumption of tramadol ● If I fail to take tramadol in a day, I take more of it the following day to cover-up

Table 3. Result of Expert Qualitative Assessment of Items

Item	Suggestion	Action taken
General Observation	Since this scale is measuring behaviour, the period within which the behaviour is measured should be specified for all the items. For example: In the past 2 months, I have been using tramadol for ……	All items were rephrased. For example: In the past 2 months: 1. I have been using tramadol without consulting a doctor. 2. I have been taking tramadol every time I had urge for sex. 3. I have been consuming more than 400 mg of tramadol in a day. 4. I have been dissolving tramadol in energy drinks before taking. 5. I have been taking tramadol if I wanted to stay long at work.

factor one, 0.604 to 0.983 for factor two, and 0.638 to 0.933 for factor three. After rotation of the factors using ProMax method, the result in the pattern matrix[a] showed that all items had factor loadings > 0.50 except Q4, Q14 and Q18 and were removed resulting in a 3-factor model with 15 items. There was no case of item cross-loading and all the pairs of factor correlation coefficients were < 0.85 indicating sufficient discriminant ability. Factor one had 7 items (Q2, Q5, Q9, Q10, Q12, Q15 and Q16) and was named Frequency of Use. Factor two had 5 items (Q3, Q6, Q11, Q13 and Q17) and was named Intensity of Use, while factor three had 3 items (Q1, Q7 and Q8) and was named Pattern of use as shown in Table 4.

Reliability of the scale

The Cronbach alpha computed to determine the internal consistency of the scale yielded reliability coefficients of 0.95 for factor one (frequency of use), 0.96 for factor two (intensity of use) and 0.89 for factor three (pattern of use) as presented in

Table 4. Result of EFA and reliability for the scale

Factors		Items	Factor loading	Cronbach's alpha
Frequency of use	2	In the past two months, I have been taking tramadol every time I had urge for sex	0.985	0.95
	5	In the past two months, I have been taking tramadol every time I wanted to stay long at work	0.655	
	9	In the past two months, I have been taking tramadol every time I got offended by someone	0.858	
	10	In the past two months, I have been taking tramadol as many times as I had urge for it	0.898	
	12	In the past two months, I have been using tramadol every time I met with my friends	0.871	
	15	In the past two months, I have been taking tramadol every night before going to bed	0.858	
	16	In the past two months, a day hardly passed without me using tramadol	0.937	
Intensity of use	3	In the past two months, I have been consuming more than 400 mg of tramadol in a day	0.991	0.96
	6	In the past two months, I have been taking any amount of tramadol given to me	0.774	
	11	In the past two months, if I failed to take tramadol in a day, I took more of it the following day to cover-up	0.947	
	13	In the past two months, I have been competing with friends to know who consumes highest amount of tramadol	0.939	
	17	In the past two months, I have been taking any form of tramadol available	0.950	
Pattern of use	1	In the past two months, I have been using tramadol without consulting a doctor	0.968	0.89
	7	In the past two months, I have been dissolving tramadol in energy drinks before taking	0.795	
	8	In the past two months, I have been using tramadol whether I have pains or not	0.828	

Table 4. This indicates that the scale had good internal consistency as the three factors had reliability coefficients > 0.70 (Taber, 2018).

DISCUSSION

There are indications that the practices or behaviour relating to tramadol use have not been measured with valid and reliable tools in the past. In an effort to understand tramadol abuse and its underlying nature better, a self-report 15-item scale has been developed to measure pattern of tramadol use, frequency of use and intensity of use. This scale was named 'Tram-BEHAV'. The result of the analysis has shown that the scale has adequate and relevant items to measure tramadol abuse. The result has also shown that the Tram-BEHAV items were clear and understandable to the target group with satisfactory psychometric properties and good reliability.

Although several tools have been developed to measure pharmaceutical opioids abuse, to the best of the researchers' knowledge, this is the first that is specifically measuring tramadol abuse. Unlike the PDUQ (Compton et al., 2008), the POMAQ (Coyne et al., 2018) and the POMI (Knisely et al., 2008), that measure abuse of opioids generally with no mention of tramadol, the Tram-BEHAV measures tramadol abuse only. Another area of distinction that could be noticed between the previous opioids abuse measurement tools and the Tram-BEHAV is that while the former tools used patients with chronic pain for validation purposes and are strictly used in clinical settings, the later used tramadol users in the community setting who were not necessary experiencing pain. This implies that the scale could be applied in a non-clinical setting to assess the needs for a community-based intervention in tramadol abuse.

By measuring the pattern of tramadol use as covered by the Tram-BEHAV, it will be easy to ascertain if one is using tramadol without consulting a doctor or over-the-counter use of the drug as reported by Olsson, Öjehagen, Brådvik, Kronstrand and Håkansson (2017). It will also determine the use of tramadol for purposes other than pain treatment like sex, work performance and mood enhancement as reported by Fuseini et al. (2019). The measurement of the frequency of use will indicate the extent of addiction to tramadol which defies the recommended three times that tramadol should be taken in a day (morning, afternoon and evening) but depends on the frequency of the non-medical needs and compulsive cravings (Condron, 2016). The measurement of intensity of use will help to identify excessive (dangerous) use of tramadol if the responses to the items are affirmative. According to Winstock, Borschman and Bell (2014), the consumption of tramadol (even for a medical purpose) in excess of the maximum recommended dose of 400 mg in a day is dangerous. The scale specification of the time frame (two months) within which the abuse behaviour is being measured is equally important in identifying only those who are current tramadol abusers.

CONCLUSION

A 15-item scale in a self-report format that is valid in content with satisfactory psychometric properties and good internal consistency has been developed

to measure tramadol abuse based the underlying constructs of pattern of use, frequency of use and intensity of use. The scale can be used to identify tramadol abuse practices or behaviour in both clinical and non-clinical settings for possible intervention efforts. It can also help to determine the content of the intervention programs for effective implementation. The Tram-BEHAV could as well be used for the evaluation of intervention programmes in tramadol abuse.

LIMITATIONS

The potency of the Tram-BEHAV to measure change in tramadol abuse after an intervention has not been evaluated. It is, therefore, important that its' potency should be studied before subjecting it to a wider application. The factor structure of Tram-BEHAV has also not been verified by confirmatory factor analysis (CFA) due to the inability of the researchers to access a large sample required for the CFA. It is recommended that CFA should be used in future to confirm the construct validity of the Tram-BEHAV.

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