Development and Psychometric Validation of a Scale for Measurement of Attitudes Towards Tramadol Use

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Abstract

Evidence in the literature have pointed that to date, there is no scale with satisfactory psychometric properties to measure attitudes towards tramadol use. The objective of this study was, therefore, to develop and validate a scale that would fill this vital existing gap in the measurement of attitudes towards tramadol use. The scale items (n = 28) were sourced from the literature and focus group discussions with tramadol users. Six experts and 30 long-term tramadol users were engaged for content and face validations of the items respectively. For construct validation, 192 tramadol users were engaged. 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. Four items failed to meet the item-content validity index (I-CVI) cut-off point (I-CVIs < 0.83) and were deleted leaving 24 items with the scale-content validity index (S-CVI) of 0.94. Five more items were deleted for cross-loading and low loading values (loadings < 0.50) leaving 19 items. The EFA resulted in the extraction of three factors: perceived benefits (11 items), perceived threat (6 items) and willingness to quit (2 items) with the reliability coefficients of 0.91, 0.96 and 0.92 respectively. We named this scale Tram-MIND because it has to do with the feelings and emotions of the mind towards tramadol use. Tram-MIND can provide vital information for developing appropriate attitudinal change interventions and could as well be used for outcome evaluation of the intervention measures.

Keywords: Development, validation, scale, questionnaire, attitudes, tramadol abuse

Introduction

Tramadol is a prescription opioid indicated for moderate to moderately severe pains. It is often used as an analgesic agent to treat specific pain conditions such as post-operative and obstetric pain, back pain, neuropathic pain, arthritis, and post-trauma (Ogbemudia et al., 2022; Varrassi et al., 2019). Tramadol was initially thought to have minimal addictive potentials compared to other opioid analgesics, but recent unfolding scenarios have proved contrary (Ibrahim et al., 2018; Saapiire, Namillah, Tanye, & Abubakari, 2021). For instance, Molobe, Yesufu, Idigbe, and Ibe (2023) reported high addictive potentials of tramadol as

reflected in the subjects' craving for the drug shortly after its half-life. Another study found that tramadol has a clear risk of producing high abuse potential under infrequent long-term use and high doses (Yassa & Badea, 2019).

Tramadol has become a leading drug for abuse in many countries across the globe. For instance, high prevalence of tramadol abuse (55.7%) has been reported in Iran (Nasiri et al., 2019). Another study reported tramadol as the most abused opioid in Sweden with 26% prevalence (Herrnsdorf, Holmstedt, & Håkansson, 2022) and in Egypt, it has been reported that about 40.7% of Egyptian drug users use tramadol (Ahmed et al., 2018). In China, 27.3% prevalence has been reported (Wang et al., 2018). In Nigeria, 4.6 million people were reported to have abused tramadol (National Bureau of Statistics, 2018). The high prevalence of tramadol abuse could be attributed to the energetic, euphoric, and aphrodisiac effects of the drug leading to its' illicit production to meet the high demands especially among the youths (Fuseini, Afizu, Yakubu, & Nachinab, 2019; Molobe et al., 2023).

The alarming rate of tramadol abuse by young people has posed several health challenges globally, ranging from mild effects such as headache, stomach-ache, itchy skin, and painful urination to severe long-term effects such as psychiatric disorder, seizure, serotonin syndrome, cardiovascular collapse, and respiratory depression (El-Hadidy & Helaly, 2018; Sansone & Sansone, 2019). A report on drug use shows that 450,000 people died in 2015 worldwide because of drug use. Out of that figure, 167,750 deaths were linked to drug use disorders in most cases involving misuse of pharmaceutical opioids like tramadol, morphine, and codeine (United Nations Office on Drugs and Crime, 2018). In Iran, 34.6% cases of seizures and mortality involving tramadol misuse were reported (Rostam et al., 2020). In Northern Ireland, it was reported that tramadol abuse-related deaths represented 48% of all deaths associated with drug abuse (Faria et al., 2018). Tramadol abuse has been associated with increased mortality in South Korea resulting from renal and hepatic damages (Jeong, Tchoe, Li, & Shin, 2019). Tramadol abuse has also been linked to acts of violence and criminality. For example, cases of robbery, rape, stabbing and Boko Haram activities were reported to have been fuelled by tramadol abuse in Gabon, Ghana, and Nigeria (British Broadcasting Corporation, 2018; Ebo, 2018). These threats to health, wellbeing, and security attributed to tramadol abuse demand an urgent response.

Attitude refers to a set of emotions, beliefs, and feelings towards a particular object, person, thing, or event (Kendra, 2020). Attitudes can have a powerful influence over behaviour. According to Kendra (2020), while attitudes are enduring, they can also change. Attitudes are developed in such a way that one cannot hold both positive and negative attitudes towards an object or event concurrently (Ajzen, Fishbein, Lohmann, & Albarracín, 2018). Attitudes are usually considered falling along a unidimensional continuum: people may hold positive or negative evaluations of an object or event but not both. It is important to measure attitudes towards drugs because the feelings and perceptions individuals hold about specific drugs are strong predictors of substance use (Champagne, Gardner, & Dommett, 2019). The result of attitude assessment could be useful in predicting self-reported drug use among individuals (Lytle, Apriceno, & Kowal, 2020) and in evaluating outcomes of attitudinal change interventions. Due to people's diverse experiences with drug use and their various reactions, one would expect people to differ significantly in their attitudes towards drug use. People who have positive perceptions about drugs would likely use the drug, while those who have negative perceptions would probably stay away from drug use.

Even though validated scales for measuring attitudes towards drug use exist, none of these scales had measured attitudes towards tramadol use. For example, Goodstadt et al. (1978) in their 'drug attitude scale (DAS), measured students' attitudes towards the use of tranquilizers (Valium and Librium); barbiturates (Seconal and tuinal); heroine; opiates other than heroine (morphine and methadone); alcohol (wine, beer, gin, and whiskey); cannabis

(marijuana and hashish); hallucinogens (LSD, mescaline and DMT) and tobacco. Tramadol was not included in this scale may be because, it was not yet a substance of abuse. Also, the measurement of attitudes towards drugs (MAD) scale by Ross and Linn (1973), was developed particularly to define the relationship between agency staff or community attitudes and drug use. The validation study for this scale did not use actual drug users, and there was no mention of tramadol among the drugs included in the scale. Another scale based on the theory of planned behaviour (TPB) to measure attitudes towards tramadol abuse by Bashirian et al. (2014) was not psychometrically validated. Only the reliability test result was reported for the scale leaving out content, face, and construct validities. This is a proof that to date, there is no valid and reliable scale with satisfactory psychometric properties to measure attitudes towards tramadol use. We, therefore, developed and validated a scale to measure attitudes towards tramadol use.

Methods

A mixed-method design combining a qualitative study with quantitative procedures was applied. Two stages were involved in the scale development. 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 started with literature search by accessing databases (PsycINFO, PubMed, google-scholar, Drug Database, Scopus, MEDLINE, Web of science and sociological Abstracts) to see if valid and reliable instruments or scales existed for measurement of attitudes towards tramadol use. It was, however, found that there were no specific, valid, and reliable instruments for measuring attitudes towards tramadol use.

The procedure applied in constructing the scale entailed listing as many characteristic attitudes towards tramadol use as was possible. Statements typifying attitudes towards tramadol use were sourced from literature review and from focus group discussions (FGDs) with long-term tramadol users. Some of the questions asked during the FGD sessions include: "Do you see the use of tramadol as a problem to you, your family, and society?" "How do you feel when people complain about your use of tramadol?" "Have you at any point in time regretted being a tramadol user?" "How would you feel if the sale of tramadol in medicine shops is banned in Nigeria?" "What do you think about the side effects of tramadol making you stop using the drug? Responses from the FGD were used to generate items for the scale.

Second stage: Validation of the Scale

The validation of the scale was performed in three phases: content, face, and construct validations.

Content validation

The 28-item scale (draft) was emailed to six experts, including two psychologists, two addiction counsellors and two experts in test and measurement for content validation after obtaining their consents to participate in the scale validation. They were requested to rate the items using a 4-point Likert scale with values ranging from 1 (item is not relevant) to 4 (item is highly relevant) based on their judgement of the degree of relevance of each item in the measurement of attitudes towards tramadol. 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 et al., 2007).

Face validation

To ensure the clarity and comprehensiveness of the items, the draft copies of the scale were administered to 30 tramadol users. They were to rate the degree of clarity and comprehensiveness of each item using a 4-point Likert scale with values ranging from "the item is not clear and understandable (1) to the item is very clear and understandable (4)". Rating scores of 4 and 3 were converted to valid (1) and rating scores of 2 and 1 were converted to invalid (0). The scores were entered into Microsoft excel to compute item-level face validity index (I-FVI) and the scale-level face validity index (S-FVI). The cut-off point retaining items was set at 0.83 (Yusoff, 2019b).

Construct validation

A validation study was conducted for construct validation of the scale. Details of this validation study are as described below:

Sample and sampling

The scale was administered to 192 participants for exploratory factor analysis (EFA). The sample size of 192 participants was based on the Sample to Variable Ratio (*N: p Ratio* where *N* refers to the number of participants and *P* refers to the number of variables or items) recommended for scale validation studies (Williams et al., 2010). For this study, the ratio of 8:1 (8 participants per item) was applied to arrive at the sample of 192 (8 x 24 = 192). This sample size was considered sufficient for EFA. Chain-referral (snowball) sampling was applied since tramadol users were considered a special population that could not be easily accessed by other methods.

Research tool

A self-report scale was used for data collection. The scale had 24 items (after deleting four items for low I-CVI) each representing a specific attitude towards tramadol use. The response format was a 5-point Likert scale: strongly disagree, disagree, neutral, agree, and strongly agree with the corresponding numerical values of 1, 2, 3, 4, and 5. Higher score represents positive attitudes towards tramadol use, while lower score represents negative attitudes towards tramadol use.

Data collection method

The method of administration was face-to-face. After recruitment of the participants by chain-referral, several meetings with the tramadol users were scheduled in designated places where an explanation on the purpose of the study was given, and informed consent to participate was obtained after giving assurance of confidentiality.

Data analysis

Exploratory factor analysis was applied using IBM SPSS software version 26.0 to identify the underlying factor structure of the scale. Descriptive statistics were conducted to check for missing responses. The Kaiser-Meyer- Olkin (KMO) index of greater than 0.50 and the significant Bartlett's Test of Sphericity ($P < 0.05$) were used to determine the suitability of the data for EFA (Williams et al., 2010). The principal axis factoring (PAF) method was used to extract factors. Promax rotation method was applied to maximize high item loadings and minimize low item loadings (Tabachnick & Fidell, 2013). Parallel analysis based on Eigen values > 1.0, and a scree plot inspection were performed to determine the number of extracted factors. The factor loading cut-off point was set at 0.5 which is acceptable for a newly developed instrument (Tabachnick & Fidell, 2013), and items with loadings less than 0.5 were suppressed. For internal consistency (reliability) of the scale, Cronbach's alpha was computed, and the acceptable reliability coefficient was set at 0.7 (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

Table 1: *Demographic Characteristics of the Participants (n = 192)*

Variables	Mean (SD)	n	(%)
Age	27.9 (4.4)		
Gender			
Male		184	(95.8)
Female		8	(4.2)
Marital Status			
Single		77	(40.1)
Married		112	(58.3)
Separated		2	(1.0)
Widowed		1	(0.5)
Level of Education			
Nil/primary		5	(2.6)
Secondary		174	(90.6)
Tertiary		13	(6.8)
Occupation			
Farming		100	(52.1)
Construction		31	(16.1)
Fishing/Hunting		5	(2.6)
Transportation		37	(19.3)
Trading		10	(5.2)
White-collar job		7	(3.6)
Others		2	(1.0)
Tramadol Prescription Status			
Prescribed for me		4	(2.1)
Not prescribed for me		188	(97.9)
Duration of Tramadol Use			
< 1 Year		28	(14.6)
≥1 Year		164	(85.4)

SD = standard deviation, n = frequency

Scale development

The results of the FGD with tramadol users were used to generate 28 items for the scale (Table 2), and a 5-point Likert scale response format ranging from 1 (strongly disagree) to 5 (strongly agree) was adopted for the scale.

Table 2:   FGD Questions and Item Generation for the Scale

FGD Question	Responses	Application in the scale
Do you see the use of tramadol as a problem to you, your family, and the society?	● I do not see tramadol as a problem to me● I feel tramadol is not a problem to me because I am using it for a purpose● Tramadol is a problem to me because it is not good for me● Tramadol has not changed me● I feel happy using it because it solves my problems.	● Tramadol is not good for me● The use of tramadol is a problem to me● The use of tramadol does not change who I am● I am happy that I have found a drug for my problems
How do you feel when people complain about your use of tramadol?	● I do not feel happy about it. I think people should mind their businesses. ● Using tramadol is my business and not anyone's business. ● My use of tramadol should not be anyone's problem● I like keeping friends with only people who use tramadol● Tramadol has not changed who I am. So, I really do not care about what they say● I feel uncomfortable but do not have a choice. I think people should be discouraged from using the drug.	● I do not care what people say about tramadol● I feel uncomfortable when people complain about my use of tramadol● My use of tramadol should not be anyone's problem● I like keeping friends with only those that use tramadol● I hate people that talk bad about tramadol● I think people should be discouraged from chronic use of tramadol● People should mind their businesses and forget about my use of tramadol● People who are not tramadol users are better off.
Tell us about your willingness to live a tramadol-free life in the future.	● I am willing to stop using tramadol. ● Living a tramadol-free life will be good to me. I can do anything to stop it● I hope to use tramadol till when I die. It is just a drug that is helping me● For now, no willingness except something else happens to me to make me stop using tramadol.	● I am willing to quit tramadol use● I hope to continue using tramadol throughout my life● It is not right to ask me to stop using tramadol● Asking me to stop using tramadol is like asking me to commit suicide● I will be eager to participate in any programme that would help me quit tramadol use● I can do anything possible to stop using tramadol
Have you at any point in time regretted being a chronic tramadol user? (Probe: if yes, why?)	● I do not have regret. It is not a mistake for me to use tramadol. ● I have no regret because I have found a drug that is good for me. ● I regret being a tramadol user because it has endangered my life.	● I have no regret being a chronic tramadol user● I will ever remain grateful to the person that introduced me to tramadol● My life is in danger with chronic use of tramadol● I made a mistake for choosing to be a tramadol user
How would you feel if the sale of tramadol in medicine shops is banned in Nigeria?	● I will be very sad if they ban tramadol sale because the drug is useful● I will feel bad if they say tramadol should not be sold● If they say nobody should sell tramadol in medicine shops now, there will be problem● I will be happy if tramadol is banned. That will help me stop it.	● I will be happy if the sale of tramadol is banned● I will be sad if tramadol is not easily accessible
What do you think about the side effects of tramadol making you to stop using the drug?	● If the side effects are serious, I will try to stop. ● The side effects are just mild so they cannot stop me from using tramadol● If the side effects are serious, then I think I will try to stop except if a doctor asks me to take it.	● The side effects of tramadol cannot stop me from using the drug● Tramadol should only be used when prescribed by a health care professional.

Content validity of the scale

The result of expert validation shows that the scale items have acceptable I-CVIs (> 0.83) except Q12, Q13, Q20 and Q25 with I-CVIs of 0.67, 0.67, 0.67 and 0.5, respectively. Based on the CVI cut-off point of 0.83 for more than 5 raters (Polit et al., 2007), these items

were removed from the scale. Overall, the scale has good content validity index of 0.94 (S-CVI > 0.83. The result of the qualitative assessment of items by experts is as presented in Table 3.

Table 3: Result of the Qualitative Assessment of Items by Experts

Item	Suggestion	Action taken
Q24	People should mind their businesses and forget about my use of tramadol. Choose one.	The question was rephrased: People should forget about my use of tramadol
Q27	I will be eager to participate in any programme that would help me quit tramadol use. Rephrase the question to 'I'm willing to….'	The question was rephrased: I am willing to participate in any programme that would help me quit tramadol use.

Face validity of the scale

The result of the face validation of the scale showed that 22 items had I-FVIs greater than the cut-off point of 0.83, indicating that items were clear and understandable to the target group. Only Q12 and Q24 with I-FVIs of 0.77 and 0.80 respectively were not clear and understandable (I-FVIs < 0.83). They were, however, not removed from the scale but rephrased for better clarity and comprehension following expert suggestion. Q12 was, therefore, rephrased to read "I'm not comfortable with cautions against tramadol use" and Q24 "I will be sad if access to tramadol is made difficult". Overall, the scale has good face validity index of 0.98 (S-FVI > 0.83).

Construct validity of the scale

The result of the descriptive analysis showed there was no missing data and that the participants chose between the full range of 1-5 response options. Some items including Q1, Q2, Q4, Q6, Q9, Q10, Q12, Q15, Q16, Q18, Q19 and Q23 were reverse scored before the analysis because they were negative items. The KMO index was 0.94 and Bartlett's Test of Sphericity was significant ($P < .001$). A KMO index of 0.50 is generally considered good for EFA (Williams et al., 2010). This indicates that the data had a good KMO index and was suitable for exploratory factor analysis. The scree plot (Figure 1) indicated extraction of three factors. Table 4 presents the results of the exploratory factor analysis.
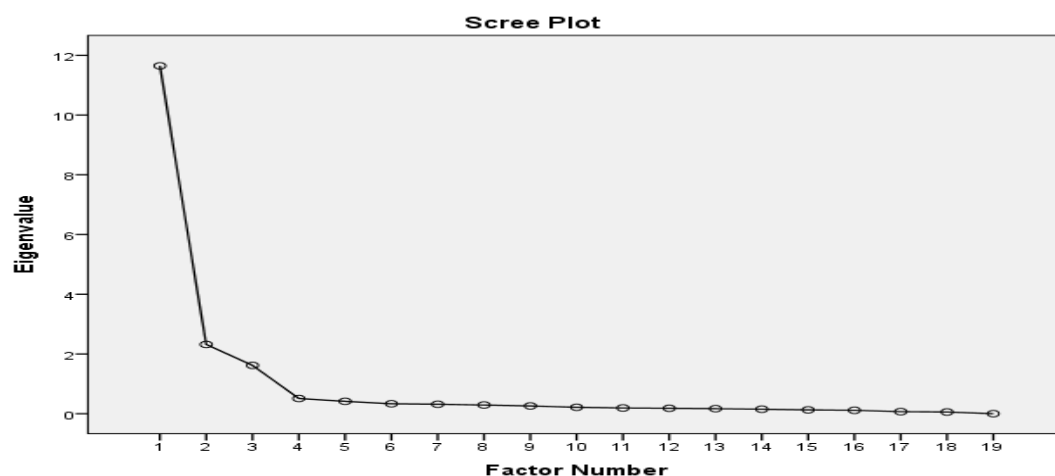

Figure 1. *Scree plot for Factor Extraction*

Table 4. Result of EFA and Reliability of the Scale

Factors		Item	Factor loading	Cronbach alpha
Perceived Benefits	3	I have no regret being a tramadol user	1.008	0.91
	5	I do not care what people say about tramadol	0.662	
	7	The use of tramadol does not change who I am	0.678	
	8	I am happy that I have found a drug for my problems	0.896	
	11	The side effects of tramadol cannot stop me using the drug	0.900	
	12	I am not comfortable with cautions against tramadol use	0.898	
	13	I hate people who talk bad about tramadol	0.844	
	14	My use of tramadol should not be anyone's problem	1.012	
	21	Peope should forget about my use of tramadol	0.783	
	22	People who use tramadol should not be regarded as drug addicts	0.832	
	24	I will be sad if access to tramadol is made difficult	0.902	
Perceived Threat	1	Tramadol is not good for me	0.986	0.96
	6	My life is in danger with the use of tramadol	0.640	
	9	I made a mistake by choosing to be a tramadol user	0.885	
	15	I will be happy if the sale of tramadol is banned	0.851	
	18	I think people should be discouraged from chronic use of tramadol	0.897	
	19	Using tramadol is the worst thing that has happened to me	0.966	
Willingness to Quit	4	I am willing to quit tramadol use	0.921	0.92
	10	I will do anything possible to stop using tramadol	0.943	

EFA resulted in the extraction of three factors with 19 items out of the initial 24 items after deleting Q2 (cross-loading), Q16, Q17, Q20 and Q23 (loadings < 0.50). Factor one with 11 items was named Perceived Benefits, factor two with six items was named Perceived Threat and factor three with two items was named Willingness to Quit (Table 4). The communalities were 0.653 to 0.989 for factor one, 0.697 to 0.949 for factor two, and 0.854 to 0.867 for factor three. All the pairs of factor correlation coefficients were < 0.85, indicating sufficient discriminant ability of the scale.

Reliability of the scale

The result of the Cronbach alpha showed that factor one (perceived benefits) had a reliability coefficient of 0.91, factor two (perceived threat) had a reliability coefficient of 0.96, and factor three (willingness to quit) had a reliability coefficient of 0.92 as presented in Table 4. The reliability coefficients of the three factors were greater than 0.70, indicating that the scale had good internal consistency (Taber, 2018).

Discussion

The result of the content validity test for this scale showed that Q12, Q13, Q20, and Q25 had I-CVIs below the cut-off point of 0.83 ((Polit et al., 2007) and were removed from the scale. The items were removed following the suggestion by Yusoff (2019a) that items adjudged not to be relevant to the measurement of a defined domain by most of the experts should be removed from the proposed scale. The result of the face validity test with tramadol users showed that out of the remaining 24 items, 22 were adjudged to be clear and

understandable by tramadol users. Only Q12 and Q24 were adjudged not clear and understandable. However, due to the relevance of the items in the measurement of the tramadol users' attitudinal characteristics, the items were not removed from the scale but rephrased following expert suggestion. The decision not to remove the items with low I-FVIs was also predicated on the fact that face validity is casual, soft, and is considered as an inactive measure of validity (Bolarinwa, 2015). Therefore, removing items based on their poor performance in the face validity test could affect the content validity of a measurement scale.

The result of EFA showed that five more items (Q2, Q16, Q17, Q20, and Q23) were removed from the scale due to cross-loading and factor loading values below 0.5 (Tabachnick & Fidell, 2013). Three factors were extracted from the EFA: perceived benefits (11 items), perceived threat (6 items), and willingness to quit (2 items). This scale was developed in a self-report format to assess attitudes of tramadol users towards the drug they use. We named this scale Tram-MIND because it has to do with the feelings and emotions of the mind towards tramadol use. Unlike DAS (Goodstadt et al., 1978) that measures students' attitudes (including those not into drug use) towards multiple drugs, Tram-MIND measures attitudes of tramadol users who may not be necessary students. Another difference between the Tram-MIND and the previous attitude scales is that Tram-MIND not a polydrug scale. By this, the scale can identify specific attitudinal characteristics of tramadol users only. In contrast with MAD (Ross & Linn, 1973), which measures the attitudes of agency staff or community towards drug use, the Tram-MIND measures attitudes of only drug users.

Conclusion

A 19-item scale with good content and face validity indices, and satisfactory psychometric properties has been developed to fill the existing gap in the measurement of attitudes towards tramadol use. By using this scale, one could determine the perception of the benefits of tramadol use, perception of its threat to health and social life, and willingness to quit for possible intervention efforts. Tram-MIND can provide vital information for developing appropriate attitudinal change interventions and could as well be used for outcome evaluation of the interventions.

Limitation

The factor structure of the Tram-MIND has not been verified by confirmatory factor analysis (CFA) due to inability of the researchers to access large sample size that is required for CFA validation studies. It is therefore, suggested that a validation study using CFA should be conducted in future to confirm the construct validity of the Tram-MIND.

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