

**DEVELOPMENT OF AN EDUCATIONAL
MODULE AGAINST TRAMADOL ABUSE
AND ITS EFFECTIVENESS AMONG
YOUTHS IN BENUE STATE, NIGERIA**

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UNIVERSITI SAINS MALAYSIA

2021

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MODULE AGAINST TRAMADOL ABUSE
AND ITS EFFECTIVENESS AMONG
YOUTHS IN BENUE STATE, NIGERIA**

by

ZWAWUA ORFEGA

**Thesis submitted in fulfilment of the requirements
for the degree of
Doctor of Philosophy**

December 2021

ACKNOWLEDGEMENT

I would like to express my gratitude to God Almighty for His protection over my life and for providing all I needed to attain a higher level of education. My sincere appreciation goes to my main supervisor, Dr. Rohani Ismail and my co-supervisors, Associate Prof. Mohd Azhar Mohd Yasin, and Associate Prof. Norhayati Mohd Noor, all of Universiti Sains Malaysia, and to my field supervisor, Prof. Targema Iorvaa of Benue State University, Makurdi Nigeria for their immense scholarly supervisory roles during the writing of this thesis.

I am grateful to Benue State University, Makurdi under the immediate past vice-chancellorship of Prof. Moses Msugh Kembe and the management of TETFUND Nigeria for finding me worthy of sponsorship for a Ph.D. programme at Universiti Sains Malaysia. I acknowledge the roles of my Heads of Department and Directors of Centre for Research Management at Benue State University, Makurdi, for always making good recommendations of me to get approval for funds from TETFUND.

I deeply appreciate my parents, wife, children, and siblings for their prayers and supports in various forms during my Ph.D. programme. I am grateful to my colleagues, friends, mates, and all Nigerian students at USM for their various supports during my postgraduate studies. I am thankful to my research assistants for helping in data collection and for administering the intervention successfully. I appreciate all the participants in this study ranging from psychiatrists, addiction counsellors, experts in various fields and tramadol users for willingly participating in this study. I am deeply grateful to Godwin Obande and Dr. Mohammed Goni, for always facilitating my registration process at USM even when I was away for data collection in Nigeria. To all those whom space has not allowed me to mention here, I say thank you, and may God bless you richly for your various contributions to the success of this thesis.

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LIST OF SYMBOLS

α	Item discrimination in EFA
b	Item difficulty in EFA
n	Frequency
p	P-value
χ^2	Chi-square
%	Percentage
$>$	Greater than
$<$	Less than
$+$	Plus
$-$	Minus
N	Nigerian Naira (currency)
\$	US Dollar

LIST OF ABBREVIATIONS

ADDIE	Analysis, Design, Development, Implementation, and Evaluation
CFA	Confirmatory Factor Analysis
CI	Confidence Interval
CVI	Content Validity Index
DF	Degree of Freedom
EFA	Exploratory Factor Analysis
Edu-MATA	Educational Module Against Tramadol Abuse
FDA	Food and Drug Administration
FGD	Focus Group Discussion
FGDCPAC	Focus Group Discussion Guide for Psychiatrists/Addiction Counsellors
FGDGTU	Focus Group Discussion Guide for Tramadol Users
FVI	Face Validity Index
I-CVI	Item-level Content Validity Index
I-FVI	Item-level Face Validity Index
IMB	Information-Motivation-Behavioural skills
KMO	Kaiser-Meyer-Olkin
LGA	Local Government Area
Mg	Milligrams
NDLEA	National Drug Law Enforcement Agency
NOWS	Neonatal Opioid Withdrawal Syndrome
PAF	Principal Factor Analysis
Q-CUDTK	Q-Cup Urine Drug Test Kit
RM ANOVA	Repeated Measures Analysis of Variance
S-CVI	Scale-level Content Validity Index
SD	Standard Deviation
S-FVI	Scale-level Face Validity Index

SMDM	Sidek Module Development Model
SPSS	Statistical Package for Social Sciences
TAPS	Tobacco, Alcohol, Prescription medications and other Substance Use
UK	United Kingdom
UN	United Nations
UNESCO	United Nations Educational, Scientific and Cultural Organization
US	United States
USM	Universiti Sains Malaysia
WHO	World Health Organization

**PEMBANGUNAN MODUL PENDIDIKAN TERHADAP
PENYALAHGUNAAN TRAMADOL DAN KEBERKESANANNYA DALAM
KALANGAN BELIA DI BENUE STATE, NIGERIA**

ABSTRAK

Tahap penyalahgunaan tramadol dalam kalangan belia di Nigeria telah mencapai satu tahap yang sangat membimbangkan dan mengatasi kadar penyalahgunaan ganja. Namun begitu, pendidikan kesihatan komuniti dan modul kaunseling ketagihan dadah sangat terhad. Kajian ini bertujuan membangun modul pendidikan bagi mencegah penyalahgunaan tramadol (*Edu-MATA*) dan keberkesanannya dalam kalangan belia di Benue State. Kajian dilaksanakan dalam tiga fasa menggunakan kaedah gabungan. Fasa pertama adalah pembentukan modul berdasarkan Model Pembangunan Modul Sidek. Kandungan modul diperoleh daripada kajian sorotan literatur dan perbincangan secara berkumpulan. Kandungan tersebut dipilih berdasarkan tiga konstruk daripada Model IMB: pengetahuan (*information*), motivasi dan kemahiran tingkah laku (*behavioural skill*). Fasa kedua melibatkan pembinaan satu alat ukur dan kajian pengesahan bagi menentukan kesahan (kandungan, muka dan konstruk) dan ketekalan (dalaman) alat ukur tersebut. Fasa ketiga adalah kajian intervensi dalam komuniti berbentuk kuasi-eksperimental untuk melihat keberkesanan modul. Peserta kajian terdiri daripada 48 orang dalam kumpulan kawalan dan 49 orang dalam kumpulan intervensi. Kumpulan intervensi mengikuti modul yang merangkumi penggunaan dan salah guna tramadol, kesan buruk, dan berhenti daripada salah guna tramadol secara selamat. Kumpulan intervensi juga dilibatkan dengan tarian aerobik bagi meningkatkan motivasi responden. Mereka turut didedahkan dengan strategi dan kemahiran mengubah sikap serta efikasi sendiri untuk

berhenti penyalahgunaan tramadol. Kumpulan kawalan pula didedahkan dengan tarian aerobik dan drama sepanjang tempoh intervensi. Analisis pengukuran berulang ANOVA digunakan untuk melihat perbezaan nilai purata untuk pengetahuan, sikap, efikasi sendiri dan tingkah laku antara dua kumpulan tersebut sebelum intervensi, dua minggu, dan tiga bulan selepas intervensi. Dapatan fasa pertama kajian menunjukkan pencapaian 85.5% kesahan dicapai dan kebolehppercayaan keofisi adalah 0.76 membuktikan Edu-MATA dan alat ukur yang dibina adalah sah dan tekal. Hasil kajian fasa dua menunjukkan semua alat penilaian (Tram-KNOW, Tram-MIND, Tram-QUIT and Tram-BEHAV) adalah sah dan tekal (internally consistent). Fasa ketiga menunjukkan peningkatan nilai purata pengetahuan berkaitan tramadol ($F = 480.6, p = .001$), pengurangan nilai purata sikap positif terhadap tramadol ($F = 360.3, p = .001$), peningkatan nilai purata efikasi sendiri untuk berhenti mengambil tramadol ($F = 185.8, p = .001$), penurunan nilai purata tingkah laku ($F = 104.1, p = .001$) dalam kumpulan intervensi berbanding kumpulan kawalan. Ini menunjukkan keberkesanan modul Edu-MATA dalam menangani penyalahgunaan tramadol. Kesimpulannya, modul ini boleh diguna pakai oleh pendidik kesihatan komuniti, promosi kesihatan, kaunselor penagihan dadah, pakar psikiatri, pegawai rehabilitasi, guru-guru, dan juga penyelidik yang berminat dengan isu penyalahgunaan tramadol dalam kalangan belia.

**DEVELOPMENT OF AN EDUCATIONAL MODULE AGAINST
TRAMADOL ABUSE AND ITS EFFECTIVENESS AMONG YOUTHS IN
BENUE STATE, NIGERIA**

ABSTRACT

Tramadol abuse among Nigerian youths has reached a worrisome level, with a projection to surpass the rate of cannabis abuse. Despite this, community educational modules on drug addiction are non-existent. The objective of this study was to develop an educational module against tramadol abuse (Edu-MATA) and test its effectiveness among youths in Benue State. The study was implemented in three phases using a mixed-method design. The first phase developed the module based on Sidek Module Development Model. The content of the module was sourced from literature review and focus group discussion. The content was selected according to the three constructs of the IMB model: information, motivation and behavioral skills. The second phase of the study involved constructing assessment tools and determining their validity and internal consistency. The third phase was a community-based intervention study using quasi-experimental design to test the effectiveness of the Edu-MATA. The study participants consisted of 49 and 48 tramadol abusers in the intervention and control groups, respectively. The intervention group received education on tramadol and the skills for quitting its abuse using Edu-MATA. On the other hand, the control group was engaged in aerobic dance and drama throughout the intervention period. Repeated measures analysis of variance (RM ANOVA) was used to test the difference in mean values for knowledge, attitudes, self-efficacy, and behaviour between the two groups before the intervention, two weeks, and three months after the intervention. The result of the first phase showed a content validity achievement of 85.8% and a reliability

coefficient of 0.76 for the newly developed module, indicating the Edu-MATA was valid and reliable. The results of the second phase showed that all the assessment tools (Tram-KNOW, Tram-MIND, Tram-QUIT and Tram-BEHAV) were valid and internally consistent. The third phase of the study showed increased mean value for knowledge about tramadol ($F = 480.6, p = .001$), decreased mean value for positive attitude towards tramadol ($F = 360.3, p = .001$), increased mean value for self-efficacy for quitting tramadol ($F = 185.8, p = .001$), and a decreased mean value for tramadol abuse behaviour ($F = 104.1, p = .001$) in the intervention group as compared to the control group after the intervention. This indicates the effectiveness of the Edu-MATA in curbing tramadol abuse. The Edu-MATA can be adopted by health promotion specialists, addiction counsellors, psychiatrists, officials of rehabilitation homes, and even researchers interested in the abuse of tramadol among the youths.

CHAPTER 1

INTRODUCTION

1.1 Introduction

The chapter one of this study opens with the background of the study and further describes the prevalence and the situation of tramadol abuse in Nigeria. This is followed by the study rationale/significance, research questions, research objectives, research hypotheses, and operational definitions.

1.2 Background of the Study

The development of any community or nation largely depends on youths who have the physical wherewithal to drive the socio-economic development sustainably. Youths are considered the first line of defense against any breach of the social fabric by maintaining values, morals, religion, and heritage of a nation (Hassan, 2013). From this standpoint, if a destructive phenomenon such as drug and substance abuse get its way among the youths in a community or nation, it will be catastrophic because stability, unity, peace, security, and development will be threatened.

Youth, as defined by United Nations Educational Scientific and Cultural Organization (UNESCO, 2014), is a period of transition from the dependence of childhood to adulthood's independency, and awareness of the interdependence as members of a community. According to this definition, youth is a more fluid category than a fixed age group. For statistical purposes, United Nations (UN) defines youths as those persons between the ages of 15 to 24 years (Chia, 2016). The UN secretariat uses the terms youths and young people interchangeably to mean age 15 to 24 years. Another definition considers youth to be a person between the ages of 15 and 35 years

(African Youth Charter, 2006). The definitions of youth in terms of age vary with nations. In Nigeria, the age bracket is 18 to 35 years, 15 to 35 years in Ghana, and in Malaysia, it is 15 to 40 years (National Youth Development Policy, 1997). Youth is a stage between childhood and adulthood, characterized by physical, hormonal, psychological, and social changes with high zealousness to experiment things, including drugs (Chia, 2016). Due to the persistent urge in young people to experiment drugs, they tend to be the most vulnerable group to drug abuse and addiction in society (Abudu, 2008).

Drug abuse and addictive behaviour are universal phenomena and are regarded in recent times as a major public health problem rapidly growing globally (Abudu, 2008; United Nations Office on Drugs and Crime, 2007). The problem of drug abuse places a significant threat to the quality of health of individuals and their families, society, and the nations (Chia, 2016). It has also been observed that the squeler of the physical, social, psychological, and economic harm derived from the abuse of psychoactive substances affects the individual user and the family and the community at large (Velleman et al., 2005).

One prominent drug associated with this trend is tramadol. It was first developed in Germany during the 1970s and introduced in the 1990s as a centrally acting analgesic with properties like codeine and morphine (Patterson, 2015). Tramadol is a prescription opioid painkiller for moderate and severe pains. It is often used as an analgesic agent to treat specific pain conditions, including post-operative and obstetric pain, back pain, neuropathic pain, arthritis, and post-trauma (Lee et al., 1993; Leppert, 2009). Tramadol has weak μ -opioid agonist properties and inhibits norepinephrine and serotonin re-uptake (Zhang & Liu, 2013). It was initially thought to have minimal addictive potentials compared to other opioid analgesics, but recent

unfolding scenarios have proved contrary (Boostani & Derakhshan, 2012). For instance, Liu et al. (1999), 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 (Zhang & Liu, 2013).

Sansone and Sansone (2009) observed that tramadol works by interacting with opioid receptors in the brain to relieve pains by increasing the levels of serotonin and norepinephrine in the brain, thus creating feelings of euphoria and well-being (the reason why many people abuse it). Long administration and abuse of tramadol have the potential to cause dependency, addiction, and severe withdrawal symptoms (Onuh, 2016; World Health Organization, 2014a). Zhang and Liu (2013) observed that due to tramadol's opioid stimulant effects, the potential for its abuse is increasingly high among young people. Tramadol abuse refers to (1) the use of tramadol more than 400 mg per day for moderate to severe pains (Drugs.com, 2018), and (2) the use of tramadol for purposes other than pain relief (Winstock et al., 2014). The second definition is synonymous with tramadol misuse, which refers to the use of tramadol for a purpose not consistent with medical or legal guidelines. Individuals who abuse tramadol for a long time tend to develop psychological dependence and may begin to experience compulsive cravings to take the drug and feel that they need it to cope with everyday problems (Condrón, 2016).

Tramadol has become a major substance of abuse among young people due to the euphoric, energetic, and aphrodisiac (sex-enhancing) effects perceived to be associated with its use (Bashirian et al., 2014; Bassiony et al., 2015; Fuseini et al., 2019). The abuse of tramadol has been reported in many countries across the globe. In the United States, 3.2 million people aged 12 or older had used tramadol for non-

medical purposes (Bush, 2013). A study using hair analysis reported tramadol as the most abused opioid in Sweden with 31% cases detected (Olsson et al., 2017). High prevalence of tramadol abuse (56%) has also been reported in Iran (Zabihi et al., 2011), 49% reported in Egypt (Mohamed et al., 2015). 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 abuse in Nigeria could be attributed partly to the non-regulation of tramadol at the international level and its' availability at low prices (less than \$1) at Nigerian pharmacies, which do not require prescription notes before selling out (Kayode, 2019). There is also illicit production of tramadol in Nigeria in addition to the huge-smuggled tablets. Since the well-known opioids such as cocaine, heroin and morphine are increasingly difficult to obtain due to the global fight against hard drugs and their expensive prices; tramadol, a prescription drug, has now become the choice of many youths for abuse because of its availability and low price in Nigeria. The report has it that in 2018, Nigerian authorities seized illegal shipments of about 2 billion tablets of tramadol at the ports (Kayode, 2019). This indicates a booming market for tramadol in Nigeria, whose youths are increasingly using the drug for non-medical purposes. Liu et al. (1999) reported that 65% of those who abused tramadol were 18 to 37 years of age, while the average age of onset of tramadol use was 24 years. This implies that youths are the most vulnerable group to tramadol abuse. The belief that tramadol serves as a remedy for premature ejaculation, extends orgasm and increases work performance has contributed to its popularity and massive use among Nigerian youths (Chikezie & Ebuenyi, 2019; Ibrahim et al., 2017; Orhero, 2018).

The alarming rate of tramadol abuse by young people has posed a serious health challenge globally. It is known to have dire health consequences ranging from

mild effects like headache, stomach-ache, itchy skin, and painful urination to severe long-term effects like psychiatric disorder, seizure, serotonin syndrome, cardiovascular collapse, and respiratory depression (El-Hadidy & Helaly, 2015; Sansone & Sansone, 2009). 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). Death rates for tramadol abuse alone as a pharmaceutical opioid are challenging to determine since it is usually grouped with other synthetic opioids such as fentanyl (Bush, 2013). The United States Substance Abuse and Mental Health Services Administration also reported that from 2005 to 2011, Emergency Department visits for tramadol-related misuse or abuse increased 250% from 6,255 in 2005 to 21,649 in 2011 (Bush, 2013). In Northern Ireland, it was reported that tramadol abuse-related deaths represented 48% of all drug abuse in 2011 (Randall & Crane, 2014). 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 (BBC, 2018; Ebo, 2018). These threats to health, wellbeing, and security attributed to misuse of tramadol demand an urgent response.

In the 21st century, Nigeria has witnessed changing trends in the pattern of psychoactive substance use with tramadol HCL emerging as a leading drug in various parts and regions of the country (Orhero, 2018). This has made the National Council on Health (NCH) in its 59th Meeting held in 2013 to put tramadol, a hitherto prescription-only-medicine under national control based on national trends of abuse, harm to public health and social well-being (Adeyeye, 2018). This was an intervention

to control supply and requires the manufacturer, importer, distributor, and retailer to document all transactions including disposal of the drug. The schedule in Nigeria regulated tramadol at 50 mg and 100 mg dosage strength, but very high dosages of 200 mg, 225 mg, 250 mg and even 400 mg have infiltrated the market (National Drug Law Enforcement Agency, 2018). Following the increasing number of young patients with drug use complications at the psychiatric unit of the Federal Medical Centre, Makurdi Benue State of Nigeria, a prevalence ascertaining study was carried out. The result revealed that 61% of youths in Benue state engaged in drug abuse combining traditional drugs, prescription drugs, alcohol, and new psychoactive substances, which has evidenced an even more dramatic picture of its consequences (Chia et al., 2015). The study found increases in risk-taking behaviour, including a significant rise in cases of drug addiction involving tramadol in Benue State.

Many factors could influence youths into tramadol abuse. A study by Geramian et al. (2012), demonstrated that the knowledge and attitudes towards influences substance abuse substance abuse. They further observed that young people abuse drugs due to lack of adequate knowledge about the harmful effects of the drugs, incorrect attitude towards drugs and addiction, presenting personal interdependence, peer pressure, satisfying the curiosity, low levels of self-confidence, inability in maintaining interpersonal communications and reducing stress. A study in western Kenya associated a lack of knowledge of the harmful effects of substances with substance abuse by adolescents (Embleton et al., 2012). Studies have shown that providing young people with accurate information about the negative effects of drug use will encourage abstinence from drug use (Holtz & Twombly, 2007; Sussman et al., 2007; Twombly & Holtz, 2008).

A study by Barati (2014), using the theory of planned behaviour also showed that attitude, subjective norms, and perceived behavioural control predicted intention to abuse tramadol among college students in West Iran. This means that in making efforts to change tramadol abuse behaviour, knowledge, attitude and perceived behavioural control or self-efficacy should primarily be modified. A study by Ibrahim et al. (2017), in north-eastern Nigeria, found that the primary reasons why subjects abused tramadol continuously were to relieve tiredness, prolong the time of sexual intercourse and the curiosity to experiment. Another study by Orhero (2018) among patients in a psychiatric hospital in Nigeria revealed that subjects used tramadol to relieve pains, feel good, relieve stress, increase physical performance, enhance sexual performance, enhance sleep, and relieve frustration. There are widespread misconceptions regarding tramadol among the general population in Africa with some viewing it as a mood enhancer, a means to increase sexual stamina or as an energy-booster during work (International Narcotics Control Board, 2018). Individuals who abuse tramadol often report that such mood-elevating properties in tramadol cause them to take higher doses of the drug or to take it more often. This points out that there is a misconception about the use of tramadol, which needs to be corrected.

Over the years, there has been growing interest in drug abuse interventions that are aimed at effecting behavioural changes. Research has shown that the behaviour regarding drug use remains unchanged unless the predictors of the behaviour are manipulated. The government of Nigeria has made several efforts in curbing the menace of tramadol abuse in the country by seizing millions of smuggled tramadol tablets at the airports and seaports, closure of pharmacies and medicine stores that are culpable and penalizing individuals that illegally trade the drug. Tramadol still finds its way in large quantities to the nook and crannies of the country. There is also illicit

production of tramadol with forged labels to meet the high consumption demands. This is a pointer that only laws, and force cannot tame the high prevalence of tramadol abuse except combining it with an educational intervention that could cause a permanent change in the youths' knowledge, attitude, self-efficacy, and behaviour regarding tramadol use.

One of the effective panaceas to drug abuse and addiction generally is drug education, which accelerates improvement in drug users by enhancing their awareness, knowledge, hope, social techniques, and behavioural, emotional, and cognitive changes (Sheykhnezhad & Seyedfatemi, 2019). Educational-related interventions enable individuals to develop the knowledge, skills, and attitudes to appreciate the benefits of living healthy (which may not include the use of psychoactive substances), promote responsibility towards the use of drugs and relate these to their actions and those of others, both now and their future lives (Tupper, 2008). These interventions are generally targeted at modifying the knowledge of individuals regarding drug use, exposing them to the health and socio-economic implications of their behaviour, as well as seeking to change their inclining attitudes towards drugs and building the self-efficacy in them to resist or quit drug use (Mahmood et al., 2018). Educational intervention may be an effective strategy in altering the beliefs held by young people concerning the use of tramadol by creating unfavourable attitudes and behaviour towards tramadol abuse. It is important to make people who abuse drugs and potential abusers aware of how the abuse can affect their minds, bodies, relationships, and functioning (Osikoya & Alli, 2006). This awareness through drug education can help them realize the potential damage that could occur, or the damage that has already occurred because of abuse of a drug. When research-based drug abuse education campaigns are implemented, they effectively reduce drug abuse prevalence. Still, they

can also reduce the cost of treating future substance use disorders. Studies have shown that for every dollar allocated towards substance abuse prevention campaigns, there is a ten-fold saving in the treatment for substance use disorders (National Institute on Drug Abuse, 2014).

Many studies have recommended the use of educational interventions to curb the menace of drug abuse in the society (Cuijpers, 2002; Espada & Hernández, 2015; Faggiano et al., 2008; Giannotta et al., 2014; McBride, 2003; Newton et al., 2017). The belief is that educational interventions would increase awareness about drug use and misuse and the consequences of drug abuse, thus paving the way for informed decision-making. Research has also shown that young people suffering from addiction are likely to return to it after receiving addiction treatment (Winters et al., 2011). This could probably be due to the lack of drug education services in their communities. The general assumption is that knowledge of the ill effects of drug abuse acquired through educational interventions can prevent addiction (Gilham et al., 1997). In other words, the more people know about drugs, the less likely they are to consume them. To be effective, educational interventions should be planned, be holistic in approach, and select and use effective methods properly (UNESCO, 1995). The intervention must be holistic because it should be developed along with the knowledge and drug information model, affective education model, social influence model and life skills model. The knowledge and information component of the drug educational intervention takes care of knowledge; the affective component which involves counselling services tackles beliefs, attitude, and skills for improving self-efficacy while the life skill component of the intervention focuses on teaching resistant skills against social pressure, developing drug problem-solving skills and decision making (UNESCO, 1995). The drug education initiatives most likely to achieve desired outcomes are based on a clear

understanding of targeted behaviours and the social context in which they occur (Tupper, 2008).

Educational interventions are best implemented with the use of modules. An educational module is a document that contains learning experiences and activities systematically organized to transmit knowledge and skills required to carry-out specific tasks for the achievement of specific objectives. A module provides a guide for the interventionist and serves as consultation material for the participants. Despite the alarming prevalence of tramadol abuse, especially among out-of-school youths in Nigeria, there is no educational material that community health educators and addiction counsellors could use to inculcate knowledge and skills required for quitting tramadol use. Even though several learning materials on drugs and substance abuse have been developed in Nigeria, they are mainly for implementation in the classroom for in-school population, relegating to the background a significant number of out-of-school population of young persons who are the most vulnerable to drugs and substance use. Besides, considering the novelty of tramadol among the drugs of abuse in Nigeria, many learning materials in schools do not have any information on it. In the light of this, the researcher has developed and evaluated an educational module to fill this essential existing gap in the fight against tramadol abuse among youths in Nigeria.

1.3 Problem Statement

Tramadol abuse and addiction have become major public health problems in recent years. An increasingly alarming phenomenon of tramadol abuse has been heavily demonstrated in Nigeria in recently (Akpan, 2016). Although drug abuse is not new to Nigerian society, tramadol has become a major substance of abuse second to cannabis with a wide range of abuse and illegal transactions as it is easily accessible

and readily provided at cheap costs (Orhero, 2018). The approved quota for tramadol in Nigeria is 6000 kg, however, the amount in circulation is about 91000 kg (Klein & Ane, 2019) far exceeding the approved quota. Kayode (2019) observed that a lot of tramadol coming into Nigeria is from illegal routes. The alleged usages of tramadol have contributed considerably to its popularity and massive use, especially among youths and middle-aged individuals, to remedy premature ejaculation, extend orgasm and increase sexual pleasure and work performance (Azenda, 2015). Report on drug use in Nigeria by the National Bureau of Statistics (2018), shows that cannabis was the most widely abused substance in Nigeria with the prevalence of 10.8% (10.6 million people) followed by pharmaceutical opioids (mainly tramadol, and to lesser extent, codeine, or morphine) with a prevalence of 4.7% (4.6 million people). The prevalence of drug use generally, as released by National Bureau of Statistics (2018), is as presented in Table 1.1.

Table 1.1

Prevalence of Drug Use in Nigeria (National Bureau of Statistics, 2018)

Drug used	Estimated prevalence. (per cent)	Low estimate (per cent)	High estimate (per cent)	Estimated numbers
Cannabis	10.8	10.3	11.3	10,640,000
Tramadol	4.7	4.3	5.1	4,608,000
Heroin	0.1	0.0001	0.2	87,000
Cocaine	0.1	0.0001	0.2	92,000
Tranquilizers/sedatives	0.5	0.0001	0.9	481,000
Amphetamines	0.24	0.0001	0.6	238,000
Pharmaceutical amphetamines	0.16	0.0001	0.5	155,000
Methamphetamine	0.1	0.0001	1	89,000

Ecstasy	0.3	0.0001	1.2	340,000
Hallucinogens	0.03	0.0001	0.8	27,000
Solvents/inhalants	0.3	0.0001	1.2	300,000
Cough syrups	2.4	1.5	3.3	2,360,000

The prevalence of tramadol abuse among youths in Benue State has steadily risen over the years. It was reported that up to 30 percent of males in Benue State between the ages of 15 and 30 had used tramadol (National Drug Law Enforcement Agency, 2018). Despite consistent border seizures of the smuggled drugs, thousands of boxes of tramadol tablets in high dosages still make their way to the rural youths who are increasingly dependent on the drug, and some were seriously addicted (Adeyeye, 2018). Consequently, the number of young patients suffering from addiction-related symptoms associated with tramadol use at Nigerian clinics and hospitals is alarming, just as many psychiatric disordered-young people roam the streets due to drug addiction (Azenda, 2015). The massive use of tramadol by the youths in Benue State and the attendant health and psychosocial consequences beats one's imagination of how the prevalence of abuse would be in few years to come if nothing is done to tame the menace.

Despite the alarming prevalence of tramadol abuse among Nigerian youths with resultant threat to public health and security, there is no educational tool that could be used by the community health educators and addiction counsellors to inculcate knowledge and skills required for quitting tramadol abuse. This study, therefore, developed, validated, and evaluated an educational module against tramadol abuse (Edu-MATA) to fill this important existing gap in drug abuse intervention research in Nigeria.

1.4 Study Rationale and Significance

The persistent increase in the prevalence of tramadol abuse among Nigerian youths with its attendant consequences ranging from health to socio-economic is worrisome and urgent action is needed in research and policy framework to curtail this menace. However, around research, literature review demonstrates the paucity of intervention studies on tramadol abuse in Nigeria. Most of the available studies dealt with the prevalence and reasons for tramadol abuse, such as its mood-enhancing effects, prolonged sexual intercourse, and relieving fatigue and anxiety (Chia et al., 2015; Ibrahim et al., 2017; Orhero, 2018). However, evidence of interventions to reduce tramadol abuse among young persons is completely missing from the available literature in Nigeria. Therefore, the present study is justifiable at this material time as it is hoped to fill up this vital gap in drug abuse intervention research in Nigeria.

1.5 Research Questions

The research questions for this study were:

1. Is the educational module against tramadol abuse (Edu-MATA) valid and reliable?
2. Are the instruments for measurement of knowledge, attitudes, self-efficacy, and behaviour regarding tramadol use valid and reliable?
3. Is there any difference in the mean knowledge scores on tramadol between the intervention and control groups at baseline, two weeks, and three months post-intervention?
4. Is there any difference in the mean attitude scores on tramadol between the intervention and control groups at baseline, two weeks, and three months post-intervention?

5. Is there any difference in the mean self-efficacy scores on tramadol between the intervention and control groups at baseline, two weeks, and three months post-intervention?
6. Is there any difference in the mean behaviour scores on tramadol between the intervention and control groups at baseline, two weeks, and three months post-intervention?

1.6 Objectives

1.6.1 General objective

The general objective of this study was to develop an educational module against tramadol abuse and assess its effectiveness among youths in Benue State, Nigeria.

1.6.2 Specific objectives

The specific objectives of this study were as follows:

Phase one (module development and validation)

1. To develop an educational module against tramadol abuse (Edu-MATA)
2. To determine the validity (content and face) and reliability of the Edu-MATA

Phase two (development and validation of measurement instruments)

3. To develop instruments for measurement of knowledge, attitudes, self-efficacy and behaviour regarding tramadol use.
4. To determine the validity (content, face, and construct using exploratory factor analysis) of the measurement instruments and their reliability (internal consistency) using Cronbach alpha.

Phase three (community-based intervention study)

5. To compare the mean knowledge scores on tramadol between the intervention and control groups at baseline, two weeks, and three months post-intervention.
6. To compare the mean attitude scores on tramadol between the intervention and control groups at baseline, two weeks, and three months post-intervention.
7. To compare the mean self-efficacy scores on tramadol between the intervention and control groups at baseline, two weeks, and three months post-intervention.
8. To compare the mean behaviour scores on tramadol between the intervention and control groups at baseline, two weeks, and three months post-intervention.

1.7 Research Hypotheses

The study hypotheses were as follows:

1. There was a significant difference in the mean knowledge scores between the intervention and control groups at the baseline, two weeks, and three months post-intervention.
2. There was a significant difference in the mean attitude scores between the intervention and control groups at the baseline, two weeks, and three months post-intervention.
3. There was a significant difference in the mean self-efficacy scores between the intervention and control groups at the baseline, two weeks, and three months post-intervention.
4. There was a significant difference in the mean behaviour scores between the intervention and control groups at the baseline, two weeks, and three months post-intervention.

1.8 Operational Definitions

For this study, the following definitions as contained in Table 1.2 were applied:

Table 1.2

Operational Definitions

Term	Definition
Knowledge	It is the youths' awareness or familiarity with the facts about tramadol. Knowledge on tramadol was assessed using Tram-KNOW with 35 questions. The overall knowledge was categorized using Bloom's cut-off point, as good if the score was up to 60%, and poor if the score was less than 60% (Yusof et al., 2018). Higher scores indicate better knowledge about tramadol.
Attitude	The way the youths think and feel about tramadol. Attitude was assessed using Tram-MIND. The overall attitude towards tramadol was categorized using Bloom's cut-off point, as positive if the score was up to 60%, and negative if the score was below 60% (Arbiol et al., 2016). Higher scores indicate more favourable attitudes towards tramadol use.
Self-efficacy	The perceived ability and capability of the youths to resist the use of tramadol in compelling situations. Self-efficacy was measured using Tram-QUIT. The overall self-efficacy was categorized as high if the score was 60% or more, and low if the score was below 60%. Higher scores indicate high self-efficacy for quitting tramadol use
Behaviour	Youths' involvement in tramadol use in terms of frequency, quantity, and pattern. Behaviour was measured using Tram-BEHAV. The overall tramadol abuse behaviour was categorized as dangerous if the score was up to 60%, and minimal if the score was less than 60%. Higher scores indicate more dangerous use of tramadol.
Youths	Young people aged 18 to 35 years (official age bracket for youth in Nigeria)
Tramadol abuse	It is (1) the use of tramadol without prescription, (2) using tramadol more than 400 mg per day for moderate to severe pains and (3) use of tramadol for purposes other than pain relief
Educational module against tramadol abuse (Edu-MATA)	A newly developed learning and skill acquisition tool on tramadol that consists of the use and abuse of tramadol and the necessary skills required for informed decision-

	making and resisting pressure to abuse tramadol. The Edu-MATA was developed using the information-motivation-behavioural skills (IMB) model. The module aims to improve the knowledge on tramadol among youths, alter attitudes that are favourable to tramadol abuse, improve self-efficacy for quitting tramadol abuse, and reduce tramadol abuse among the youths.
Effectiveness	The ability of the Edu-MATA to produce higher mean scores on knowledge about tramadol, lower mean scores on attitude towards tramadol, higher mean scores on self-efficacy for quitting tramadol use, and lower mean scores on tramadol abuse behaviour in the intervention group than the control group after implementation.
Tram-KNOW	Questionnaire for assessing knowledge about tramadol.
Tram-MIND	A scale for measuring attitudes towards tramadol
Tram-QUIT	A scale for measuring self-efficacy for quitting tramadol use.
Tram-BEHAV	A scale for measuring tramadol abuse behaviour.
Aerobic dance	A patterned form of exercise involving music. The exercise is performed according to the rhythmic of music.
Intervention group	Participants in the study belonging to the group that received information, motivation and skills for quitting tramadol use as contained in the Edu-MATA.
Control group	Participants belonging to the group that did not receive anything relating to tramadol during the intervention period

1.9 Summary

The chapter one of this study in its background, describes how tramadol has become a major substance of abuse among Nigerian youths due to its euphoric, energetic and aphrodisiac effects. The chapter further highlights non-regulation of tramadol at the international level, cheap cost of tramadol, smuggling of tramadol, illicit local production of the drug, and misinformation as factors responsible for high prevalence of tramadol among Nigerian youths with grievous health and socioeconomic effects. The chapter identifies gaps in intervention research on

tramadol abuse in Nigeria, thus justifying the need for the present study. Chapter one further highlights the objective of the study which was to develop an educational module against tramadol abuse among youths in Benue State, Nigeria and test its effectiveness in reducing tramadol abuse.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

This chapter presents a review of literature on the opinions, views, observations, and study findings related to tramadol use and abuse, effects of abuse, influencing factors and interventions. The literature review is broadly organized under conceptual and theoretical frameworks.

2.2 Brief History of Tramadol Hydrochloride

Tramadol hydrochloride was first discovered and synthesized in Germany in 1962 after a clinical trial was conducted. It was found that tramadol combined opioid and monoaminergic effects, which represented a milestone in the evolution of pain treatment (Bravo et al., 2017). It was first produced by a German pharmaceutical company known as Grunenthal GmbH, located in Stollberg, Germany, specializing in treating pains in late the 1960s. Tramadol was created with properties similar to codeine and morphine and was tested for 15 years in Germany before it was launched and brought to the foreign market in 1977 as an oral immediate-release formulation under the brand name Tramal. In the 1990s, tramadol was introduced in the United Kingdom (UK), United States (US) and Australia. In the U.S alone, tramadol prescription recorded a significant increase from 23 million in 2008 to 37 million in 2013 (International Narcotics Control Board, 2018). Since then, various formulations containing tramadol hydrochloride have been launched in more than 100 countries worldwide (Patterson, 2015) with different trade names including ultram, tramol,

analdol, boldol, camadol, domadol, zydol and so many other names (World Health Organization, 2014b).

Tramadol (popularly known as tramol in Nigeria) became available in Nigeria in 1995. The drug, a prescription drug, is being sold in Nigeria illegally as an over-the-counter medication in tablets and capsules ranging from 50 mg to 400 mg (Adeyeye, 2018). It is very cheap to obtain tramadol in Nigeria as a 10-tablet strip of 100 mg of tramadol cost ₦100 only, equalling \$0.28 (Pulse TV, 2018). It is also very easy to get the drug in Nigeria. Since it is not banned or strictly regulated, most pharmacies still sell tramadol to anybody who walks in to buy it. The regulation of tramadol in Nigeria is at 50 mg and 100 mg dosage strengths but very high dosage forms of 200 mg, 225 mg, 300 mg and even 400 mg have infiltrated Nigerian markets. There is a noticeable increase in the smuggling of tramadol tablets and capsules into Nigeria. Available information has shown Nigeria as one of the countries in the world with the highest use of tramadol relative to population (Adeyeye, 2018). There is also illicit production and adulteration of tramadol in Nigeria in addition to the huge-smuggled tablets from other countries. In 2018 report, Nigerian authorities seized illegal shipments of about 2 billion tablets of tramadol at the ports (Kayode, 2019).

2.3 Clinical Use of Tramadol Hydrochloride

Tramadol is a pharmaceutical opioid indicated for the treatment of moderate to moderately severe pains. Tramadol belongs to the class of synthetic opioids (pain relievers) which come under the class of compounds obtained from “*papaver somniferum L*” and are considered in the narcotic category which acts on the central nervous system to produce pain relief (Martínez et al., 2016). Bamigbade and Langfold (1998) observed that tramadol produces relief for moderate to severe pains across the

range of acute and chronic pain states. According to them, up to 400 mg/day tramadol has efficacy equivalent to codeine, dextropropoxyphene, paracetamol and aspirin oral combination analgesics. Desmeules (2000) discovered that the involvement of tramadol in both opioid and the monoaminergic mechanisms of pain signal transmission produces its analgesic effect. He observed that the ability of tramadol to inhibit the re-uptake of norepinephrine and serotonin significantly contributes to its analgesic activity by blocking pain impulses at the spinal level. Tramadol as an analgesic according to Subedi et al. (2019), provides relief to the three classes of pains namely, nociceptive pain (produced by tissue injury), neuropathic pain (produced by nerve injury), and neuroplastic pain (produced by musculoskeletal diseases).

Tramadol as a centrally acting analgesic with opioid agonist has been found as an effective analgesic agent for treating specific pain conditions, including post-operative and obstetric pain, back pain, neuropathic pain, arthritis, and post-trauma (Lee et al., 1993; Leppert, 2009). Tramadol is also useful in relieving labour pain, fibromyalgia, and acute dental pain (Lewis & Han, 1997; MacLean & Schwartz, 2015). Being an analgesic with weak opioid receptor affinity and possessing monoaminergic activity, tramadol has proved suitable for use in the second step of the three-step analgesic ladder proposed for cancer pain treatment by the World Health Organization (Reig, 2002). The potency of tramadol in the cancer pain treatment at the second step of the analgesic ladder was also confirmed by another study (Grond et al., 1999). Tramadol can be used to treat pain from wounds, joint pain, muscle pain and several other pain conditions. Tramadol may also be used off-label to treat premature ejaculation (PE) problem, as it inhibits the reuptake of serotonin which plays a vital role in the regulation of ejaculatory threshold (Abdel-Hamid et al., 2016). However, patients using tramadol for the treatment of premature ejaculation are likely to develop

other sexual dysfunctions (Andersson, 2011). Analgesic studies have shown that tramadol is approximately one-tenth as potent as morphine when administered parenterally, and approximately one-third as potent when administered orally (Divvela et al., 2006; Martinez et al., 2015). In clinical use, the dose of tramadol recommended for mild and moderate pain is 50 – 100 mg every six hours (Epstein et al., 2006).

However, the use of tramadol is not recommended for persons under the age of 18, and patients with a medical history of seizure, epilepsy, head injury, drug addiction, alcoholism, and metabolic disorders (Subedi et al., 2019). Tramadol should also be avoided at the early stage of pregnancy and during breast-feeding as doing so may cause congenital disabilities and harm the foetus or the breast-feeding babies (Källén & Reis, 2015). The duration of analgesia with orally administered tramadol is three to six hours, with maximum pain relief at one to four hours post-dose (Shipton, 2000).

2.4 Abuse Potentials of Tramadol

One crucial indicator of the abuse potential of any drug is the extent to which it produces the reinforcing effects (Epstein et al., 2006). A drug is considered to have abuse potential if it can reinforce behaviour, thus maintaining self-administration under experimental conditions (Willner, 1997). This means that a drug with abuse potential produces cravings and withdrawal symptoms such that users are moved to abuse or misuse them. For tramadol, the subject of its addictive or abuse potentials remains debatable. Initially, tramadol was shown to have zero or minimal addictive or abuse potentials. For example, a review of studies involving the administration of tramadol on animals and humans by Bamigbade and Langfold (1998), showed that tramadol causes minimal dependence and tolerance, and has very low abuse potential.

Dalgin (1995), also observed that physical dependence, withdrawal, tolerance, and abuse were minimal with tramadol therapy. Only a few patients tended to continue using tramadol after the treatment. Another related study found that tramadol has a low risk of abuse because it only has a weak opioid effect, and its monoaminergic action could inhibit the development of dependence (Desmeules, 2000). On a comparative basis, tramadol was a safer drug than morphine and codeine as drug abuse and dependence were of minor clinical relevance (Klotz, 2003; Preston et al., 1991).

However, there are emerging scenarios that have established that tramadol has high abuse potentials. This could partially be explained by the illicit production of tramadol and the adulteration of the product by some unlicensed pharmaceutical companies. For this reason, Bassiony et al. (2015) opined that tramadol abuse liability is being underestimated and the evidence of abuse and dependence is increasingly emerging daily. A review of studies and the clinical case reports on the abuse potential of tramadol by the United State Department of Health and Human Services (HHS) showed that the studies and the case reports described abnormal behaviour that demonstrates an addiction and abuse liability of tramadol: drug craving, increasing the tramadol dose, inflicting self-injury to be prescribed more tramadol, taking high doses despite experiencing adverse effects, and visiting multiple physicians to obtain more prescriptions for tramadol (Drug Enforcement Administration, 2013). The abuse potential of tramadol was also confirmed by Liu et al. (1999) in their assessment of tramadol's drug dependence and abuse liability of tramadol among 219 opiate addicts. They found that the subjects had a strong craving for tramadol after a short period of non-use. They concluded that tramadol produces high abuse potential among opiate addicts.

Similarly, in their letter to the editor, Pollice et al. (2008) reported severe tramadol addiction in a 61-year-old woman without a history of substance abuse. They observed that some patients might continue to take tramadol “to achieve a feeling of wellbeing” even after controlling their pain. One randomized study using nine non-dependent prescription opioid abusers reported an increase in measures indicative of the abuse liability of tramadol after 4-weeks of self-administration (Babalonis et al., 2013). The study concludes that higher doses of tramadol could reinforce abuse in humans. Improved mood and euphoria associated with tramadol have also been reported as inducing the abuse of the analgesic to improve mood as if it were a stimulant (Ferrari et al., 2014). A survey conducted to assess the drug dependence and abuse potential of tramadol among subjects with no history of substance abuse in China, reported that tramadol has a clear risk of producing high abuse potential under the infrequent long-term use and high doses (Zhang & Liu, 2013).

In a related development, Stoops et al. (2012) observed that high doses of tramadol produce abuse potential signals with an increase on some prototypic measures such as “liking” and increase in street value ratings. Even in therapeutic doses, Gibson (1996) warned that tramadol should not be administered to opioid-dependent patients or patients who tend to drug abuse or dependence. It is because tramadol can re-initiate physical dependence in patients who have been previously dependent or chronically using other opioids. A study among a group of experienced drug users in New Delhi, India, established that tramadol has abuse potentials even in therapeutic doses (Das et al., 2016). Another cohort study to determine chronic use of tramadol after acute pain episode found that people who received tramadol alone after surgery had somewhat higher risks of prolonged use than those who received other short-acting opioids (Thiels et al., 2019). Similarly, Zacny (2005) observes that even