



**VALIDITY AND RELIABILITY STUDY OF MALAY
VERSION BRIEF TREATMENT OUTCOME MEASURE
(BTOM) AS A TREATMENT OUTCOME MEASURING
TOOL FOR METHADONE MAINTENANCE THERAPY
(MMT) SERVICE IN MALAYSIA**

BY

MUHAMAD NAZRIN SYAFIQ BIN KHAIRI

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degree of Master in Pharmaceutical Sciences
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International Islamic University Malaysia**

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ABSTRACT

Methadone Maintenance Therapy (MMT) is one of the harm reduction approaches meant to curb illicit opioid use in the country. Instruments such as brief version World Health Organization Quality of Life (WHOQOL-BREF) and Opioid Treatment Index (OTI) are currently being used in clinical practice to measure the treatment outcomes of MMT. However, they were quite lengthy and most importantly they do not comprehensively evaluate the severity of opioid dependence among clients. The Brief Treatment Outcome Measure (BTOM) is an instrument developed to evaluate the treatment outcomes of clients attending to addiction treatment program such as MMT. To date, there is no research done relating to the cultural adaptation of the BTOM in Malay-speaking population. The objective of this study is to develop, translate and modify a Malay-version of the BTOM as a potential tool for treatment outcome evaluation among MMT patients. This study employed a cross-cultural adaptation study. The original BTOM was modified by applying cross-cultural adaptation procedures to suit to Malaysian context and cultures. The procedures comprised of conducting forward and reverse translation, synthesis of the translations, evaluation of the synthesized version by experts committee, discussion with original authors and pilot study on 30 eligible clients. The assessment covered the aspect of semantic, idiomatic, experiential and conceptual equivalences. Several terms that were not common in Malaysian setting, were omitted and replaced. Terms that are unlikely to be easily understood by clients were rephrased and further explained. 109 eligible clients were recruited into the study from five Health clinics in Kuantan area. Internal reliability of the BTOM in the actual study reported an overall unsatisfactory internal reliability for SDS ($\alpha = 0.34$) and SFS ($\alpha = 0.14$), while the remaining BTOM scores were satisfactory. Factor analysis on SDS showed good item construct, while SFS showed unfavorable item construct. The cross-cultural adaptation procedures conducted yielded a final Malay-version BTOM instrument. However, only BBVER, ODUS, Health Scale and PFS can be used in future studies, while SDS and SFS require further investigation to attest their psychometric properties in Malaysian population for clinical practice and research.

خلاصة البحث

يعتبر العلاج بجرعات الميثادون المستمرة (MMT) أحد أساليب الحد من الضرر التي تهدف إلى الحد من استخدام الأفيونات غير القانونية في البلاد. لقياس نتائج علاج MMT في المماؤسات السريرية يتم استخدام أدوات مثل الإصدار الموجز لاستبيان منظمة الصحة العالمية عن جودة الحياة (WHOQOL-BREF) واستبيان مؤشر علاج الأفيونات (OTI). ولكن هذه الأدوات تأخذ الكثير من الوقت، والأهم من ذلك أنها لا تقيم بشكل شامل شدة الاعتماد على الأفيونات بين العملاء. مقياس النتائج العلاجية الوجيز (BTOM) هي أداة تم تطويرها لتقييم النتائج العلاجية للعملاء الذين يحضرون إلى برامج علاج الإدمان مثل MMT. حتى الآن لا يوجد أي بحث متعلق بالتكيف الثقافي لمقياس BTOM في المجموعة الناطقة باللغة الملايوية. كان الهدف من هذا البحث هو تطوير وترجمة وتعديل نسخة باللغة الملايوية للـ BTOM كأداة لتقييم النتائج العلاجية بين مرضى MMT حيث استخدم هذا البحث دراسة تكيفية عبر الثقافات. تم تعديل أداة BTOM الأصلية من خلال تطبيق إجراءات التكيف بين الثقافات لتناسب مع السياقات والثقافات الماليزية. تألفت الإجراءات من الترجمة الأمامية والعكسية، وتوليد الترجمات، وتقييم النسخة المعدلة إلى لجنة من الخبراء، والمناقشة مع المؤلفين الأصليين، ومن ثم إجراء دراسة تجريبية على 30 عميل مؤهل. غطى التقييم جانب التكافؤات الدلالية، والاصطلاحية، والتجريبية، والمفاهيمية. تم حذف واستبدال العديد من المصطلحات التي لم تكن شائعة في الوسط الماليزي، وتم إعادة صياغة المصطلحات التي من غير المرجح أن يفهمها العملاء بسهولة وتم شرحها أكثر. تم إشراك 109 عميلاً مؤهلاً في البحث من خمس عيادات صحية في منطقة كوانتان. كانت الموثوقية الداخلية للـ BTOM في الدراسة الفعلية غير مرضية بشكل عام للـ SDS ($\alpha = 0.34$) وللـ SFS ($\alpha = 0.14$)، في حين كانت نقاط الـ BTOM المتبقية مرضية. أظهر تحليل العوامل على الـ SDS بناء جيداً للبنود، في حين أظهر الـ SFS بناء غير مرغوب به للبنود. أنتجت إجراءات التكيف بين الثقافات التي تم إجراؤها نسخة نهائية للإصدار الماليزي لأداة BTOM. ومع ذلك فإنه لا يمكن استخدام سوى أدوات BBVER، وODUS، ودرجة الصحة، وPFS في الدراسات المستقبلية، بينما تتطلب الـ SDS و SFS المزيد من التحقيق لإثبات خصائصهما السيكومترية في المجموعة الماليزية من أجل الممارسات والأبحاث السريرية.

APPROVAL PAGE

I certify that I have supervised and read this study and that in my opinion, it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a thesis for the degree of Master in Pharmaceutical Sciences (Pharmacy Practice)

.....
Nor Ilyani binti Mohamed Nazar
Supervisor

.....
Zaswiza binti Mohd Noor
Co-Supervisor

I certify that I have read this study and that in my opinion it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a thesis for the degree of Master in Pharmaceutical Sciences (Pharmacy Practice)

.....
Ramli bin Musa
Internal Examiner

.....
Wan Sazrina binti Wan Said
External Examiner

This thesis was submitted to the Department of Pharmacy Practice and is accepted as a fulfilment of the requirement for the degree of Master in Pharmaceutical Sciences (Pharmacy Practice)

.....
Norny Syafinaz binti Ab Rahman
Head, Department of Pharmacy
Practice

This thesis was submitted to the Kulliyah of Pharmacy and is accepted as a fulfilment of the requirement for the degree of Master in Pharmaceutical Sciences (Pharmacy Practice)

.....
Che Suraya binti Mohd Zin
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DECLARATION

I hereby declare that this thesis is the result of my own investigations, except where otherwise stated. I also declare that it has not been previously or concurrently submitted as a whole for any other degrees at IIUM or other institutions.

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This thesis is dedicated to my beloved mother, my late father, my little brother and my whole family who granted me the gift of their unwavering belief in my ability to accomplish this goal and had laid the foundation of what I turned out to be in life; thank you for your support and patience

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LIST OF ABBREVIATIONS

AADK	Agensi Anti Dadah Kebangsaan
ART	Anti Retroviral Therapy
ATS	Amphetamine Type Stimulant
BBVER	Blood Borne Virus Exposure Risk
BTOM	Brief Treatment Outcome Measure
C&CC1M	Cure and Care Clinic 1 Malaysia
CBT	Cognitive Behavioural Therapy
CCA	Cross Cultural Adaptation
CCRC	Cure and Care Rehabilitation Centre
CCSC	Cure and Care Service Centre
CDDC	Compulsory Drug Detention Centre
CRC	Clinical Research Centre
DOT	Direct Observation Therapy
DSM	Diagnostic and Statistical Manual of Mental Disorders
GCP	Good Clinical Practice
GP	General Practitioners
HIV	Human Immunodeficiency Virus
ICF	Informed Consent Form
IUM	International Islamic University Malaysia
IRB	Institutional Research Bureau
IREC	IUM Research Ethics Committee
JKNP	Jabatan Kesihatan Negeri Pahang
KK	Klinik Kesihatan
KMO	Kaiser-Meyer-Olkin
MDG	Milennial Development Growth
MMT	Methadone Maintenance Therapy
MOH	Ministry of Health
MOHA	Ministry of Home Affairs
MREC	Medical Research Ethics Committee
NADA	National Anti Drug Agency
NMRR	National Medical Research Register
NSEP	Needle Syringe Exchange Program
ODUS	Occasion of Drug Use Scale
OMP	Opioid Maintenance Pharmacotherapy
OST	Opioid Substitution Therapy
OTI	Opioid Treatment Index
PFS	Psychological Functioning Scale
PUS	Puly-Drug Use Scale
PWID	People Who Inject Drug
QOL	Quality of Life
RTG	Rawatan Terapi Gantian
SDS	Severity of Dependence Scale
SFS	Social Functioning Scale
SPSS	Statistical Package for Social Sciences

SPUB	Sistem Pendispensan Ubat Bersepadu
SUD	Substance Use Disorder
UNODC	United Nation Office of Drug and Crime
URHR	Ukuran Ringkas Hasil Rawatan
USFDA	United States Food and Drug Administration
WHO	World Health Organization
WHOQOL-BREF	World Health Organization Quality of Life

CHAPTER 1

INTRODUCTION

1.1 SUBSTANCE USE DISORDERS AND ITS GLOBAL TREND

Substance abuse has been one of the major ‘headache’ that is happening worldwide and particularly, in Malaysia. World Health Organization (WHO) defines substance abuse as an act of harmful and hazardous use of psychoactive substances including illicit use of drugs and alcohols (World Health Organization, 2016). Meanwhile, in the Diagnostic and Statistical Manual of Mental Disorders, Fifth edition (DSM-5), the term substance abuse has no longer been used to define the current situation, rather the term Substance Use Disorders (SUD) is more profoundly being used. SUD happens when the recurrent use of drugs and/or alcohol has caused significant impairment clinically and functionally to an individual, such as disability, health problems and failure to meet major responsibilities at work, school or home. The diagnosis is made based on the number of diagnostic criteria evidently met by an individual (American Psychiatric Association, 2013).

World Drug Report 2016 by United Nation Office on Drugs and Crime (UNODC) reported that it is estimated that one in twenty adults, or one quarter of a billion people with age ranges from 15-64 years old has at least used one drug in 2014 (*World Drug Report*, 2016). This trend of drug usage has been consistent globally over the last four years. Of the total number of people who use drugs, 12% or over 29 million people are estimated to suffer from SUD. Cannabis continues being the most frequently used drugs by approximately 129 – 190 million people, followed by amphetamine-type stimulants (ATS), opiates and cocaine (*World Drug Report*, 2016). Despite being the

less popular choice in the ranking, opiates ranked the top place for harmful consequences related to their use (*World Drug Report, 2010, World Drug Report, 2016*)

The overall depiction of drug use across the globe is amalgamated by the fact that many people who use drugs regularly and recreationally incline to be poly-drug users. This refers to the use of more than one substance at the same time or one after another, with the intention of potentiating, enhancing or concentrating the effects of another drug (*World Drug Report, 2016*). A long standing usage of illicit drugs has caused significant neurological changes in the brain and this may include tolerance and desensitization of dopaminergic receptors. Continuous consumption of same amount of drugs does not give same euphoric and 'high' effects anymore, unless a greater dose of drugs are administered (Lobmaier, Gossop, Waal, & Bramness, 2010). This will happen in a later stage where continuous and compulsive use of drugs is merely to sustain drug dependence in a person, despite evidence of harmful consequences. Putting a stop to this habitual use of drug, on the other hand, will lead to experiencing withdrawal or negative adverse effects.

Of about 12 million people who inject drugs (PWID) in the world, 14% of them or about 1.6 million are living with human immunodeficiency virus (HIV) and about 6 million are living with Hepatitis C (*World Drug Report, 2016*). As many as 1.2 million people are living with HIV in the United States and every one in three persons with HIV was a current drug user or binged on alcohol, as Centres for Disease Control and Prevention (CDC, 2016) reported. PWID are the population who are at-risk and vulnerable to contracting HIV and Hepatitis C, and several studies had shown that people who inject stimulants are exposed to more risky sexual behaviours resulting to higher chance to acquire HIV infection (*World Drug Report, 2016*). PWID had

contributed to 16% of HIV transmission incidence due to less frequent use of condoms and risky injecting behaviour (Vicknasingam & Mazlan, 2008; *World Drug Report*, 2016). Different parts of the world noted dynamic spread of HIV infection, especially among PWID. World Drug Report 2010 recorded highest concentration of HIV-positive PWID in South-East Asia, Latin America and Eastern Europe with more than 40% greater than other nations with PWID population (*World Drug Report*, 2010).

According to HIV/AIDS infections statistics by Resource Centre of Malaysian AIDS Council, as much as 61 943 people were found to have HIV infections through injection of drugs from 1986 to 2009. In a report from 2010 by Ministry of Health (MOH) Malaysia, it is estimated that 22.1% of around 170 000 people in Malaysia were living with HIV (World Health Organization & Ministry of Health Malaysia, 2011). After Vietnam, Malaysia came in second with the highest HIV prevalence among adult population and also highest proportion of HIV infection related to injecting drug use (Hasanah, Naing, & Rahman, 2003; Vicknasingam & Mazlan, 2008). Most of them were Malay males and these numbers keep increasing by year (“HIV Statistics,” 2011) as also shown by *Agensi Antidadah Kebangsaan* (AADK) of Malaysia (AADK, 2015; Vicknasingam & Mazlan, 2008). Six out of nine new cases of HIV recorded every day in 2009 are likely to have contracted HIV via injecting drugs use, while the remaining three are through sexual activities (World Health Organization & Ministry of Health Malaysia, 2011). This alarming situation may be caused by unprotected penetrative sex and direct blood contact through sharing of drug-injection equipment among the drug abusers, which remain as the principal mode of transmission of diseases among them (Mohamad, Bakar, Musa, Talib, & Ismail, 2010). The condition is further worsened when they are pregnant and spread the virus to their children. These have driven to

many health, social, behaviour and criminality problems to the substance abusers as well as to the community and the nation.

1.2 MEDICINE-BASED TREATMENT POLICY IN MALAYSIA

There are several possible approaches in combating drug addiction and HIV transmission; which cover different scope of goals – from total abstinence to harm reduction. Abstinence-based approach has been practiced in Malaysia to curb drug addiction problem until the middle of 2005 before the policy shifted to harm reduction approach. As outlined in the Millennium Development Goals (MDGs) in combating the epidemic of HIV, Malaysia had employed a different method in 2005 as incorporated in its National Strategic plan on HIV/AIDS 2006-2010 (World Health Organization & Ministry of Health Malaysia, 2011). Among others, the key approach was to encourage implementation of harm reduction approach since the total abstinence is no longer a doable method. Previously, the Ministry of Home Affairs (MOHA) was in charge of the portfolio of drug addiction treatment, where long-term imprisonment was the first line approach based on the abstinence-based model. Later in 2005, the Ministry of Health (MOH) has taken over the portfolio where medical treatment was provided as part of the harm reduction approach (Vicknasingam & Mazlan, 2008). Among the treatment and rehabilitation options available in Malaysia are Needle and Syringe Exchange Program (NSEP), medicine based therapy or opioid substitution therapy (OST), antiretroviral therapy (ART), condom programs for PWID, vaccination for viral hepatitis (diagnosis and treatment) and cognitive behavioural therapy (CBT) (World Health Organization & Ministry of Health Malaysia, 2011).

Needle and Syringe Exchange Program (NSEP) is a program that is implemented where used needles and syringes should be sent by PWID to the nearest selected health centres and would be exchanged for new ones. This consequentialist strategy observes the method as reducing the social and medical consequences of drug use. Sharing behaviour of injecting equipment among drug abusers would indulge them into devastating complications such as contracting HIV infection (Vicknasingam & Mazlan, 2008). Thus, this method reduces this possibility.

Medicine based therapy has been known for its effectiveness and adverse effects. It was all started when the government had taken a closer look at the treatment options when institutional treatment and rehabilitation program had not yield an effective outcome. In 1998, a nationwide study on an opioid-receptor antagonist medication, Naltrexone, was carried out onto 2029 opioid addicts which later shown high compliance towards the medication. However, the subjects had only showed slightly positive outcome as compared to placebo (Vicknasingam & Mazlan, 2008). In 2001, an opioid-receptor agonist medication, Buprenorphine mono-tablet was introduced and had effectively treated about 30000 heroin abusers. There were challenges ahead where the issue of buprenorphine misuse, unsupervised use of the medication by patients, poor medication compliance as well as no provision of counselling and other psychosocial services aroused. By the end of 2006, availability of buprenorphine mono-tablet is limited and has been changed to buprenorphine-naloxone tablet (Vicknasingam & Mazlan, 2008). Meanwhile, in the middle of 2005, another opioid-receptor agonist medication, Methadone, had been introduced into Malaysian health market known as Methadone Maintenance Therapy (MMT). It is currently being a part of drug substitution therapy under the national harm reduction program in addition to psychosocial approaches.

1.3 PROBLEM STATEMENT

The use of methadone had been accepted globally and proven effective. Many countries across the globe had implemented the use of methadone treatment and abundance of studies had been conducted to measure and evaluate its effectiveness. Numerous established instruments were used. Methadone clinics run under the supervision of MOH, including Health Clinics, have been using Opiate Treatment Index (OTI) and brief version of World Health Organization Quality of Life (WHOQOL-BREF) as the instruments and standard format for assessing and monitoring the treatment outcome of the patients (Bahagian Kawalan Penyakit, 2016). The instruments had been reputedly and widely used in many studies as having good psychometric criteria (Musa, Abu Bakar, & Ali Khan, 2012; Padaiga, Subata, & Vanagas, 2007). Despite the wide coverage of aspects of treatment outcomes through the domains they implemented, however, the instruments do not evaluate the level of drug dependency and how severe it could be. This is particularly important when we are to tailor a specific rehabilitative treatment and counselling sessions for a specific client having difference in severity of dependence (Lawrinson, Copeland, & Indig, 2005).

Brief Treatment Outcome Measure (BTOM) is an established and comprehensive instrument to evaluate the effectiveness of methadone treatment among patients. BTOM serves as a means to provide suitable and appropriate care for client needs through its thorough evaluation. It covers wide aspects of treatment outcomes in the domains of severity of dependence, poly-drug use, occasion of drug use, blood borne virus risk exposure, health, psychological, and social functioning. BTOM has not been used widely for the moment and it has potential to be used as standard instrument for assessing treatment outcome in MMT. It has been validated in Australia previously. Nevertheless, several domains and options in the original BTOM are not suitable to

Malaysian setting. This may due to limited testing of the instrument across different populations and language and cultural barrier of Australian to be used in the target population. Thus, a cross-cultural adaptability (CCA) procedure (Beaton, Bombardier, Guillemin, & Ferraz, 2000; Borsa, Damásio, & Bandeira, 2012) has been carried out onto the original BTOM instrument in this study. The process includes forward translation, reverse-translation, synthesis of the translations, evaluation of the synthesized version by experts and target population for content validity, and pilot study for reliability testing. The actual study expands the field of study to more study subjects after consideration and amendments of the Malay-version BTOM during the pilot study. It is carried out to validate the Malay-version BTOM through construct validity.

1.4 SIGNIFICANCE OF STUDY

There are numerous studies discussing on the treatment outcomes of MMT centres, particularly in MOH facilities such as government hospitals and health clinics, using several different assessing tools. However, there are no study in these facilities using BTOM as an assessment instrument. With complementary addition of several domains in BTOM as compared to OTI and WHOQOL-BREF, hence BTOM will be highly anticipated as reliable instrument to be used in evaluating treatment outcomes in MOH facilities. Besides, comprehensive implementation of CCA in adapting the questionnaire into Malaysian setting will set as a stepping stone to many future researches in validating BTOM to be used in Malaysia. It also provides significant constructive and practical execution to many CCA efforts done in Malaysia while giving an insight to many current guidelines on CCA worldwide. This study extends the verification of use of the original BTOM instrument in different set of culture and language in Malaysia. Since the original version has not been used outside Australia,

validity and reliability study is required. It is highly anticipated that this study will contribute to produce a validated and comprehensive Malay-version of BTOM and can be used as an assessing tool for treatment outcome evaluation. It will improve data evaluation and help healthcare professionals to tailor better treatment modalities for specific patients. Plus, patients are also anticipated to have a positive treatment outcome in terms of severity of dependencies, blood borne exposure risk, poly drug use, health, psychological and social functioning.

CHAPTER TWO

LITERATURE REVIEW

2.1 OPIOID USE DISORDER

2.1.1 Opioid

Opioids can be categorized into three main subclasses; namely opiates, synthetic opioids and semi-synthetic opioids. Opiates are chemical substances that are naturally derived and extracted from opium poppy and as a subgroup within opioids (Monwell & Gerdner, 2017). This may include morphine and codeine. Synthetic opioids such as methadone and fentanyl are chemically manufactured, while semi-synthetic opioids such as oxycodone and heroin are derived from chemical modifications of natural opiates. Synthetic and semi-synthetic types of opioids mimic the action of opiates by binding onto the opioid receptors (μ , κ , δ) in the body. Through this binding, opioids exert analgesic effects whereby pain symptoms are relieved. However, negative side effects such as physical dependence, drowsiness and narcosis may also appear (Monwell & Gerdner, 2017). Opioids such as morphine and tramadol are commonly prescribed as painkiller in hospital settings in Malaysia. There are also non-prescription opioid such as heroin that are commonly exposed to drug abuse through injection. Heroin is a more potent opioid analgesic, has faster onset and has shorter duration of action as compared to morphine (Rahimi-Movaghar et al., 2013). This had made heroin posed a greater threat in contributing to opioid addiction and social menaces due to its superior potency and illegality. Unsupervised use of the opioids may lead to devastating states of opioids abuse which may harm the health of a person.