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# Effectiveness of Islamic Rehabilitation Intervention Module (ISRIM) on Reduction of Cravings and Relapses among Opioid Dependents in FELDA Communities in Jengka, Pahang, Malaysia: A Study Protocol

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## ABSTRACT

**Background:** Relapse among Methadone Maintenance Treatment (MMT) clients is common especially in FELDA settlements. Since majority of MMT clients are Malay Muslims, Islamic Rehabilitation Intervention Module (ISRIM) develop in accordance with Health Belief Model (HBM) framework can be implemented as intervention for relapse prevention in FELDA communities.

**Material and methods:** A parallel, two arms, single blinded cluster randomized control trial utilizing simple randomization will be conducted, involving 10 MMT clinics clusters. The intervention group receives ISRIM for one session per week for four consecutive weeks, while control group will be on wait-list. Primary outcome is relapse status, measured monthly for six months follow-up by the first positive urine using drugs rapid test. Descriptive and inferential statistics will be done by using Statistical Package for the Social Sciences (SPSS) version 25.0. Multivariate analysis will be done using Generalized Estimating Equations (GEE), adjusted for clustering effect. Intention-To-Treat (ITT), Per Protocol (PP) analysis, interaction terms, constructs terms and key assumption terms with the level of significance set at 0.05 and confidence interval at 95% will be utilized as part of the component of sensitivity analysis.

**Results:** It is expected that ISRIM will reduce the proportion of relapse among opioid dependents in intervention group as compared to the control group, indicating the effectiveness of ISRIM.

After 2, 12, 24, 48 hours pain was felt accordingly in 54%, 38.5%, 16.8%, 10.6% cases and it was moderate ($p<0.05$). 1 week and 1 month after the PCI procedure 7.5% of patients felt strong site pain. Chronic pain developed in 3.7% of patient and it was moderate. Compilations were arterial bleeding (9.3%), hematoma (26.7%), hand swelling (66.5%) and neuropathy (6.32%).

**Conclusion:** It is hoped that from the effectiveness of the intervention, ISRIM could be incorporated into MMT programme as an adjunct intervention to reduce relapse among opioid dependents.

# INTRODUCTION

Drug dependence is a complex health condition, requires long-term treatments, imposing a heavy burden on public health system in terms of management, care, prevention of disorder and their health consequences. Globally, it is estimated that a quarter of billion people or 5% of adult population aged between 15 to 64 years old, had used illicit drugs in 2015. Over 11% of people who used illicit drugs are estimated to suffer from drug dependence and will require treatment [1]. Situated close to golden triangle (Thailand, Myanmar, Laos), there are extensive rise in the number of new and relapsing drug users in Malaysia [2]. National Anti-Drugs Agency (NADA) reported that the most common drugs of abuse in this country are opioids (53.5%), methamphetamine (31.8%), Amphetamine-Type Stimulants (ATS) (10.7%) and ganja (3.9%). Opioid dependence is one of the major social problems in Federal Land Development Authority (FELDA) settlements in Malaysia. This issue had been reported through mass media, however there is limited information gathered through scientific researchers. The largest FELDA settlements in Malaysia are located in Jengka, Pahang, comprised of three districts namely, Jerantut, Temerloh and Maran which collectively consists of 37 FELDA settlements under its administrative area. Jerantut has the highest prevalence of registered drug abuser compared to other area in the country. Local data for Jerantut in 2016 showed that the total number of registered drug abuser with NADA Jerantut, Pahang is 910 people which 640 people (70.3%) were from FELDA settlements.

There are various strategies made available for opioids dependence such as methadone treatments, detoxification, behavioural therapies and motivational programs. Methadone Maintenance Therapy (MMT) is a substitute treatment for opioids-dependent patients to relieve them from narcotic craving, suppress the abstinence syndrome and block the euphoric effects associated with opioids. Methadone will relieve the craving associated with opioids dependence in which craving is a major cause for relapse. MMT is the most commonly used intervention for opioids dependent individual in FELDA settlements in Jengka, Pahang. However, relapse is common among those on MMT programme, with many clients continuing to use opioids during and after MMT, irrespective of whether this is preceded by an initial period of abstinence or not. One of the strongest predictors of relapse is drug craving which is the intense, urgent feeling of needing or wanting drugs. Craving is much more resistant to treatment compared to physical dependence. The most recent report showed an increase in number of relapses among drug abusers, from 6,379 cases in 2015 to 7,921 cases in 2016 [3]. Relapse is defined as any usage, intake or misuse of psychoactive substance after one had received drug addiction treatment and rehabilitation whether physically and psychologically. Concomitant use of opioids in combination with MMT will increase risk of abnormal cardiac conductivity, overdose and death.

One of the efforts that have been undertaken by the government and the private sector to treat and rehabilitate drug addicts in Malaysia is through religious-based programme. NADA had started implementing treatment and rehabilitation of drug addicts through religious means in a few rehabilitation centres in Malaysia. Religion is one of the protective factors for drug relapse, buffering individuals from engaging in addictive substances and practices. Religion also plays a role in the recovery process, being seen as a peace of mind, a new life, a protector and as an encourager and motivator. Combining MMT with religious-based intervention can be useful in helping opioids dependent patients to stop using opioids, prevent relapse and return to a more stable and productive life. Several studies had reported that religious-based intervention can be compatible with the harm reduction approach in the sense that both emphasized on collaboration, empathy, individualized goal setting and spiritual therapy, especially when the method considers Islam and the Holy Quran's recommendations.

Interventions that can change human behaviour towards a particular issue are highly effective when it is driven by theoretical model. Health Belief Model (HBM) is commonly used for preventive health behaviours, sick role behaviours and clinical use. It consists of six constructs, namely perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action and self-efficacy which will help to predict the action taken by people to prevent medical conditions. HBM is a framework for motivating people to take positive health actions that uses desire to avoid negative health consequence as the prime motivation. HBM can be an effective framework to use when developing health education strategies. Since majority of Malay are Muslims, by adopting HBM, Islamic Rehabilitation Intervention Module (ISRIM) can be implemented as intervention for relapse prevention in the community.

## Objectives

**General objective:** To develop, implement and evaluate the effectiveness of Islamic Rehabilitation Intervention Module (ISRIM) using Health Belief Model (HBM) in reduction of cravings and prevention of relapse among opioids dependent Malay males in FELDA communities in Jengka, Pahang.

**Specific objectives:**

- To identify and compare the socio-demographic characteristics (age, education level, marital status, employment status, monthly income) as well as factors associated with relapse (age of onset of opioids, smoking status, alcohol consumption, peer influence, self-esteem, stress level and religious personality) of respondents in intervention and control group at baseline.

- To identify and compare the relapse status, drug craving level, perceived susceptibility, perceived severity, perceived benefit, perceived barrier, cues to action and self-efficacy level of the respondents in intervention and control group at baseline.
- To develop the Islamic Rehabilitation Intervention Module (ISRIM) using Health Belief Model (HBM) for the intervention group.
- To implement the Islamic Rehabilitation Intervention Module (ISRIM) using Health Belief Model (HBM) among opioid dependent Malay males in Methadone Maintenance Treatment (MMT) clinic in FELDA communities in Jengka, Pahang.
- To measure the effectiveness of the Islamic rehabilitation module using Health Belief Model (HBM) in occurrence of relapse within and between intervention and control group at baseline, post-intervention and six-months follow-up after controlling for covariates.
- To compare total craving score and health belief model construct scores (perceived susceptibility, perceived severity, perceived barrier, perceived benefit, cues to action and self-efficacy) within and between intervention and control group at baseline, post-intervention and six-months follow-up after controlling for covariates.

## MATERIALS AND METHODS

### Study Location

This study will be conducted in Jengka, Pahang, about 170 km from Kuala Lumpur (capital city of Malaysia). It comprised of a triangle area in the three districts namely, Jerantut, Maran and Temerloh, which encompassed an area of 64,117.05 hectares of plantations and 4,924.98 hectares of settlements area. Jengka consists of 37 FELDA settlements area with a population of 15,000 of first generation of settlers [4]. There are 10 MMT clinics for opioid dependent clients under two health district office, namely Pejabat Kesihatan Daerah Jerantut and Pejabat Kesihatan Daerah Maran that cater for 37 settlements areas.

### Study Design

This study is a parallel, single blinded cluster randomized controlled trial with pre-intervention, post-intervention and six months follow-up evaluations. An overview of the study design using CONSORT statement is described in **Figure 1**.

### Randomization

Simple randomization method will be used in this study based on geographical location of the health clinics. The target population of this study are opioids dependent Malay males, who reside in FELDA and registered with MMT program in Ministry of Health's clinics. Each of the clinic have approximately 60 to 70 registered MMT's clients.

Majority of the individuals were self-presented opioids dependence who referred to MMT clinic to quit their opioids addiction by taking daily syrup methadone. Unit of allocation is the cluster (clinic). Random allocations of the clinics to either intervention or control group is done through balloting process conducted in each clinic. Doctors in charge of each clinic will randomly pick the envelopes which has been divided the clinic into intervention arm and control arm [5]. Five of the clinics are randomly allocate to intervention arm and the other five to the control arm.

### Allocation Concealment

In this study, allocation concealment will be used, in which the act of randomization and the person recruiting participants are separated. A random table of numbers will be used to generate allocation sequence and sealed, opaque white envelopes containing 2-inch by 2-inch color-coded cards (red for 'intervention' group and white for 'control' group), placed in a wrapped sheet of aluminums foil will be used to execute the assignment. The size and weight of each envelope are identical. Doctors in charge of the MMT clinic are unaware whether intervention or wait-list has been offered in their clinic.
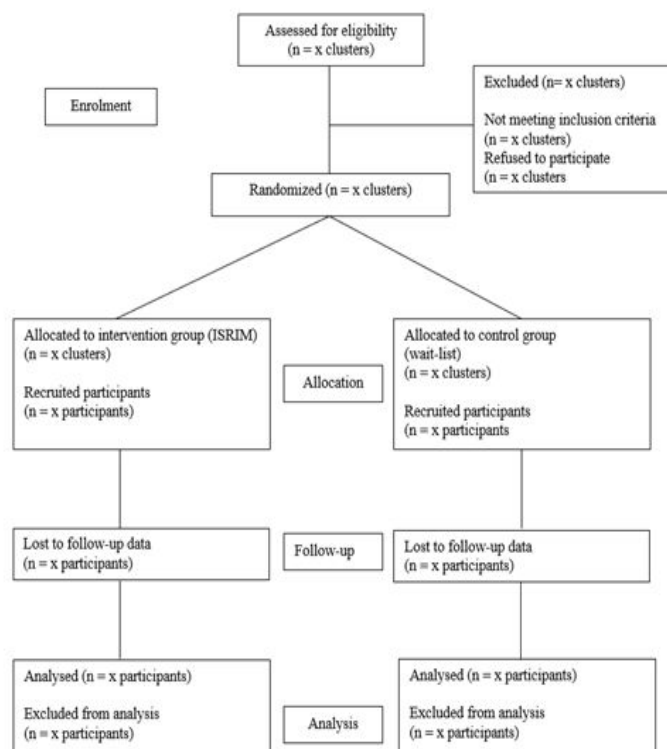


**Figure 1:** Flow chart diagram of the study using CONSORT statement.

### Blinding

This study is a single blinded as the subjects are unable to detect randomization procedure [6]. As the locations of the clinics are far from each other, subjects also may be unaware of the intervention that had been offered in other clinics.

### Study Population

Malay males who registered with MMT clinic in FELDA settlements in Jengka, Pahang will be included as a study population. The inclusion criteria include Malaysian citizen, aged between 18 to 60 years old and resides in FELDA settlements based on home address.

The exclusion criteria are individual who registered in Malaysia Cure and Care Clinic in Sg Ruan, Pahang started from Mac 2015 onwards or had received religious-based services or any similar treatment to the religious-based intervention, poor compliance to rules of MMT programs (defaulted treatment three times, violence against staff or other patients-from written MMT clinic records) and having physical limitations (bedbound, stroke patients). The sampling frame is the lists of all MMT clinics in FELDA settlement in Jengka, Pahang while the sampling unit is the opioid dependent individual registered with MMT clinic and resides in FELDA settlements in Jengka, Pahang [7].

### Sample Size Estimation

The sample size estimation is based on sample size determination in health studies by Lwanga and Lemeshow. Two populations proportion formula is used, comparing two groups for hypothesis testing. The values for differences in proportion of relapse between intervention and control group at 195 days post intervention are 0.364 and 0.636 respectively, based on a study by Pashaei, et al.

The value of Intracluster Correlation Coefficient (ICC) is 0.05 based on a study by Li, et al. Given the power of 80% to detect a true difference with 95% confidence and 20% attrition rate, the sample size required after adjusting for clustered design effect is 310 participants, with 155 participants and 5 clusters on each arm.

### Data Collection

Baseline, post-intervention and 6-months post intervention data collection will be done by using a validated, self-administered questionnaire written in Malay language. The questionnaire will have six sections, namely section A: Sociodemographic characteristics, section B: Social history, section C: Opioids history, section D: Factors associated with opioid relapse, section E: Health belief model constructs and section F: Drug craving measures.

For section D on peer influence, the questions are adapted from Steinberg and Monahan's resistance to peer influence scale. Self-esteem questions are adapted from Rosenberg self esteem scale. Stress level questions are adapted from perceived stress scale and religious personality scale question are adapted from Muslim Religiosity-Personality Measurement Inventory (MRPI).

For section E on health belief model construct, the formulation of question is based on all the constructs of HBM [8]. For section F on desire for drug and obsessive-compulsive drug use scale, the questions are adapted from Franken, et al.

Relapse status is defined as any usage, intake or misuse of psychoactive substances after one had received drug addiction treatment and rehabilitation. Relapse is measured based on the first opioid-positive urine for drug screen during the study's 6-month follow-up period.

### Data Analysis

The data in this study will be analyzed by using SPSS 25.0 for Windows. Normality of data will be checked by using histogram, skewness/standard error, Kolmogorov-Smirnov and Shapiro-Wilk normality test. This study will used descriptive statistics to summarize the participants' demographic and baseline characteristics.

Continuous variables will be expressed using mean (standard deviation) and categorical variables using percentage. T-tests (for continuous variables) and Pearson's *chi-square* tests (for categorical variables) will be used to compare participant characteristics between intervention and control groups [9].

Paired sample t-test and repeated measures analysis of variance (RM-ANOVA) will be used to compare differences between pre-intervention, post-intervention and follow-up scores within and between the intervention and control groups. Missing data will be handled by multiple imputation using Iterative Markov Chain Monte Carlo method.

The primary outcome, relapse status will be measured based on the first opioid-positive urine for drug screen during the study's 6-month follow-up period. As the primary outcome is repeated measures of relapse status which is binary data, *chi square* test, paired t-test and Cochran Q test were used.

Multivariate analysis will be done using Generalized Estimating Equations (GEE), adjusted for clustering effect. Intention-To-Treat (ITT), Per Protocol (PP) analysis, interaction terms, constructs terms and key assumption terms will be utilized as part of the component of sensitivity analysis [10]. All statistical tests are two-sided and a p-value of less than 0.05 will be considered as statistically significant.

### Quality Control

The questionnaires will be translated from English to Malay language by a group of language experts from Malaysian Translator Association (MTA), which is the sole professional non-governmental organization that deals with translation services. Back translation from English to Malay language also will be done by MTA.

For content validity, the questionnaires will be submitted to the panel of experts in Universiti Putra Malaysia for evaluation to ensure the contents of questions fulfill the requirement of the study.

For face validity, the questionnaire will be evaluated by interviewing MMT clients in FELDA Lurah Bilut in Bentong, Pahang. This sample is located far away from the study population. Respondents will be asked to give feedbacks on the clarity of the language, its appropriateness, level of understanding and comprehensiveness of the questions [11].

Based on the understanding and comments by the experts and the respondents, the questionnaires will be modified to improve the quality of this study. For reliability, pre-testing of the questionnaire will be done to approximately 10% of the total sample size (n=31). Cronbach's alpha will be analyzed for reliability in terms of internal consistency. Test and retest were done two weeks apart to look at the scale's intraclass correlation coefficient.

## RESULTS

### Islamic Rehabilitation Intervention Module (ISRIM)

**ISRIM development: Figure 2** shows a schematic diagram for the development of Islamic Rehabilitation Intervention Module (ISRIM). The intervention module will be developed through the process of consultations with a group of experts from National Anti-Drug Agency (NADA), Ministry of Health (MOH), Universiti Putra Malaysia (UPM) and Majlis Ugama Islam dan Adat Resam Melayu Pahang (MUIP) Daerah Jerantut. HBM constructs have been incorporated in the final module.
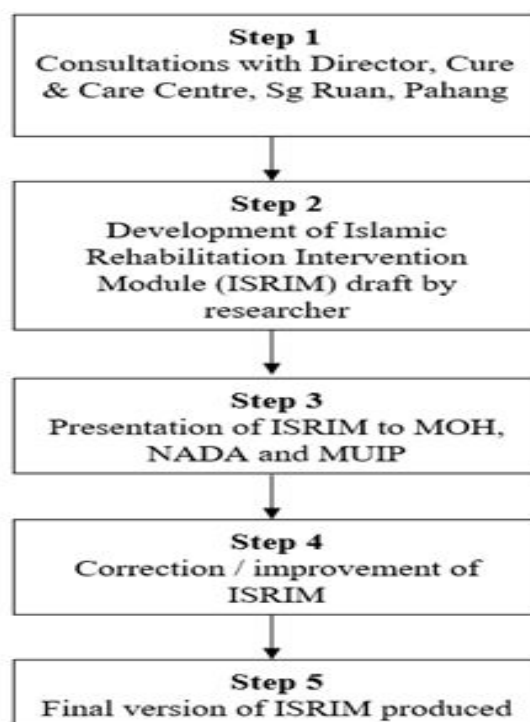


**Figure 2:** Steps in development of intervention module.

**ISRIM implementation:** The intervention group will be received ISRIM in four sessions over four consecutive weeks. To increase the attendance to the intervention, participants are free to come either on Saturday or Sunday during the weekends. The control group will be placed on a wait-list. The module will be delivered fully in Malay language and will be done by two person which are the researcher and a research assistant, who is an expert in Islamic studies. The structures and format of each session is presented in **Table 1**.

**Table 1:** Summary of ISRIM and its contents.

| Session | Duration | Activities | Content | HBM target construct | Delivered by |
|---|---|---|---|---|---|
| 1 | 90 minutes | Lecture | Introduction to SRIM | Perceived susceptibility | Researcher |
| | | | Introduction of drugs and relapse | Perceived severity | Research assistant |
| | | | Relapse and health consequences | Perceived benefit | |
| | | | Drugs in the perspective of Islam | | |
| | | | Importance of obligatory prayer, fasting and remembrance ("zkir") to Allah SWT | | |
| 2 | 90 minutes | Islamic teaching and group discussion | Taubat | Perceived benefit | Research assistant |
| | | | Obligatory prayers | Cues to action | Researcher |
| | | | Aloud (jahar) and silent (khafi) remembrance | | |
| | | | Mass remembrance practice | | |

| | | | | | |
|---|---|---|---|---|---|
| 3 | 90 minutes | Role play and group discussion | Mass remembrance practice | Perceived barrier | Research assistant |
| | | | Identify high risk situation and triggers | Cues to action | Researcher |
| | | | Discuss the nature of cravings | Self efficacy | |
| | | | Develop action plan for coping with high risk situation and cravings | | |
| | | | Islamic ways to manage craving | | |
| | | | Practice for refusal skills | | |
| | | | Managing and challenging negative thought | | |
| 4 | 90 minutes | Sharing moments | Problem solving skills | Cues to action | Research assistant |
| | | | Mass remembrance practice | Self-efficacy | Researcher |

**ISRIM evaluation:** Both the intervention and control group will be compared at baseline, post-intervention and at six months follow-up. To ensure adherence, reminder of the practice in the module will be done at monthly basis by text messaging or WhatsApp application for the intervention group after the intervention and before the follow-up at 6 months.

## DISCUSSION

Islamic Rehabilitation Intervention Module (ISRIM) aimed to facilitate participants of the trial in reduction of relapses and cravings. Islamic teaching in ISRIM consists of lectures, group discussion and hands-on sessions covers the constructs of health belief model which includes perceived susceptibility, perceived severity, perceived barrier, perceived benefit, cues to action and self-efficacy. It will fill in the gap and complements what the participants lacked in at baseline [12].

To assess the effectiveness of ISRIM on reduction of cravings and relapse among opioid dependents, a cluster randomized trial was selected as the study design. As it was assumed that there is a violation of independence of observation among opioid dependence in the same clinic, this trial was designed and commenced in a way that to control for this clustering effect. The trial follows the CONSORT statement with extension for cluster randomized trial.

In order to reduce biases and adjust the effect of known and unknown confounder, randomization was done. Ten clusters by clinics were randomized into 5 intervention and 5 control groups. Blinding in this trial is single blinded only, as the researcher himself delivered ISRIM.

Contamination will be reduced by randomizing different MMT clinics at different FELDA areas in Jerantut and Maran, Pahang. Even though there are still possibility of contamination through accidental meeting up of both groups, it was unavoidable. Hence, any variation in the outcome or unexplained variances was probably due to unmeasured confounding factors [13].

Threat to internal validity are taken into consideration in this trial. The threat by history is when there are unanticipated events occur between the data collection period. In this trial, the control group participants might attend other similar religious programme and had input on religious practices apart from the wait-list intervention module. But, if the history threat occurs for both intervention and control group, the difference between the two groups will not be due to the history events. Second threat to internal validity is maturation, in which participant's change during the course of the trial. As the final data collection will be 6-months post intervention, the religiousness increases with age. The period of maturation or ageing of the participants may had an upward drift in religious intensity and beliefs. However, as the trial is two-group design, assuming that participants in both groups change (mature) at the same rate, the threat can be negligible. Pre-testing of the questionnaires may sensitize participants in unanticipated ways and their performance on the post-test may be due to the pre-test, not to the intervention given or more likely interaction of the pre-test and the intervention. One of the ways to reduce the threat is to re-arrange the questionnaires. However, as both intervention and control groups are exposed to the pre-test and so the difference between groups is unlikely due to pre-testing.

Statistical regression is also one of the threats to internal validity in this trial. Participants who scored the worst at baseline may perform better at post-intervention as it is likely that the score regress towards the mean on the post-intervention, rather than the effect of the intervention alone. The amount of statistical regression is inversely related to the reliability of the questionnaires.

Selection bias may occur in this trial as the clusters may not be equivalent at the beginning of the study. By rule, if clusters are equivocal and selected by random sampling and random assignment, all had equal chance of being in intervention or control groups. Thus, to solve the selection bias is by using permuted block randomization method rather than a simple randomization method.

Resentful demoralization may occur if participants learn that their group received less desirable goods or services, compared to other groups. Thus, their performance may be at abnormally low level and this will increase the magnitude of difference between their performance and the other groups that receive desirable goods or services. In this trial, using wait-list intervention on the control group may eliminate the resentful demoralization among participants in control group.

## CONCLUSION

In summary, this cluster randomized controlled trial attempt to provide evidence for effective interventional module in improving relapse among opioid dependents. This intervention could be incorporated into Methadone Maintenance Treatment (MMT) as an adjunct programme to reduce relapse among opioid dependents. This trial utilized individual analysis that are adjusted for clustering effect. Hence, the intervention can be utilized at any clinic or rehabilitation center. Besides, this study utilized theory-based module development, in which each of the construct will be tested. Besides, this study utilized sensitivity analysis as well, taking into account different conditions which might affect the final results.

## ETHICAL CONSIDERATION

This study obtained approval from Medical Research and Ethic Committee, Ministry of Health on 28th September 2018 (KKM/NIHSEC/P18-1678(11)) and from Jawatankuasa Etika Universiti untuk Penyelidikan Melibatkan Manusia (JKEUPM) on 8th January 2019 (UPM/TNCPI/RMC/1.4.18.2). Permission to conduct this study will be obtained from Jerantut Health District Office and Maran Health District Office. Written informed consents will be obtained from the respondents before participation in this study. Respondent's information will be kept as strictly confidential and their identities will be kept anonymous.

## ACKNOWLEDGEMENT

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