Evaluation of the Intensive Treatment and Rehabilitation Program for Residential Treatment and Rehabilitation Centers (INTREPRET) in the Philippines: A Study Protocol for a Randomized Controlled Trial

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Study protocol

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Abstract

Background: The Philippines is one of the most severely affected countries by the methamphetamine epidemic in the world. The government launched a war on drugs policy to counter the situation in the country. However, brutality against drug users was criticized internationally. Thus, we have developed a comprehensive treatment program for methamphetamine users based on cognitive-behavioral therapy (CBT) and are going to evaluate its effectiveness. If its effectiveness is demonstrated, it will be helpful to implement much more effective and humane approaches to drug issues in the Philippines.

Methods: Methamphetamine users who are admitted to government-run rehabilitation facilities are recruited and are randomly assigned either to the CBT-based treatment program or existing therapeutic community (TC)-based treatment. The CBT treatment program was developed based on the Matrix model considering the cultural and social factors in the Philippines. After 6-months treatment, participants will be followed up for 3 months and drug use (urine testing) and other psychological variables including craving, coping skills, and well-being will be compared.

Ethics and dissemination

Informed consent will be obtained from study participants prior to study participation. Ethical approval was obtained from research ethics review boards in both countries. This study was approved by Single Joint Research Ethics Board of the Department of Health, Republic of the Philippines (SJREB-2019-27) and the University of Tsukuba Faculty of Human Sciences Ethics Committee (T2019-70). 1). Potential participants will be given a summary of the study and a consent form. The consent form is signed and dated by participants prior to their study participation. Findings of this study will be submitted for publication in international scientific peer-reviewed journals and be presented at academic conferences.

Trial registration number: UMIN Clinical Trials Registry JPRN-UMIN000038597. Registered on 15 November 2019.

Protocol version February 13, 2020 ver.1

Strengths And Limitations Of This Study

- This is the first randomized trial to compare the residential CBT program and the TC model for methamphetamine users in the Philippines.
- The comprehensive CBT program was developed considering cultural and social factors in the Philippines to treat methamphetamine users, and its effectiveness is evaluated. Additionally, Tagalog versions of psychometric scales were developed to measure outcomes.
- Therapists have been trained prior to the study and treatment integrity will be monitored during the study using a fidelity checklist.
- If the effectiveness of the treatment program is demonstrated, anti-drug campaign and brutality against drug users may be detoured.

- The blinding of participants in terms of innervations they receive may be impossible due to the nature of the intervention. However, research assistants who are responsible for recruiting possible participants and for data collection are adequately blinded.

Background

1.1. Background

Methamphetamine epidemic has been expanding globally, especially in south-east Asia over the past two decades. The methamphetamine seizure in the region was 1,000 tons in 2018 and this is five times larger than in 2013 [1]. The Philippines is one of the most severely affected countries in the region and drug abuse has been considered as one of the major public health concerns in the country. The national statistics indicates that the prevalence rate of illegal drug use was estimated to be 2.3% of the population or equivalent to 1.8 million in 2015 within the age ranges of 10-69 [2].

Under these circumstances, President Rodrigo Duterte declared a war on drugs and launched the nationwide anti-drug campaign in 2016, involving dismantling clandestine methamphetamine laboratories and arresting drug suppliers [3]. In the wake of national anti-drug campaign, approximately 1.8 million drug users surrendered to the authority and sought for treatment and social support [4]. This unprecedented demand for drug use treatment services highlighted the knowledge gaps as well as the capacity gaps of existing services. It is urgent to develop evidence-based treatment considering cultural and social background of the country. It is estimated that 1% of the surrendered deemed as high-risk users [5] and usually these high-risk users have multiple treatment needs and are subject to intensive treatment.

The Department of Health (DOH) is responsible for providing residential treatment for high-risk drug users and operates 12 Treatment and Rehabilitation Centers (TRC) nationwide. They heavily rely on the therapeutic community (TC) model. TC is very popular in this region but to date no solid evaluation has been made because it has wide variability in practice and current meta-analysis fail to find significant benefits on the rehabilitation of drug users [6].

Cognitive-behavioral therapy (CBT) is commonly used to treat individuals with drug problems in the world, especially in Western countries. However, there is no decisive evidence for amphetamines use disorders due to a lack of high-quality research [7]. CBT is to address multiple treatment needs of drug users including building skills to resist drug use, replacing drug-using activities with constructive and rewarding activities, improving problem-solving skills, and facilitating better interpersonal relationships [8,9].

The Matrix Model is specifically designed CBT-based treatment model to treat stimulant users and has been evaluated many times in several countries not only in the US [10-12], but also in Asian countries such as Japan and Iran [13, 14].

We developed the comprehensive CBT treatment program based on the Matrix Model considering cultural and social factors of the Philippines to treat methamphetamine users in the TRC and named it Intensive Treatment and Rehabilitation Program for Residential Treatment and Rehabilitation Centers (INTREPRET).

1.2. Aims and objectives

This study aims to fill existing knowledge and capacity gaps by introducing the INTREPRET in the Philippines and to compare it to existing TC-based treatment by a parallel group randomized controlled trial on subsequent drug use and psycho-social well-being. Our optimal goal is to establish the evidence-based residential treatment model for national dissemination, the findings of the study are expected to bring long-term benefits to high-risk drug users and communities alike by informing whether the treatment model works in the Philippine residential setting or there need further improvement before treatment model scales it up nationwide. Moreover, this study results will direct the policymakers toward the introduction of the more effective treatment and thus contribute to the improvement of the treatment services of drug users in the country and to prevent further non-humane countermeasures against drug users.

Methods

2.1. Overview

The trial design is parallel group randomized control trial. The study protocol was developed by authors of this paper (chaired by the first author) following the CONSORT Statement [15] and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [16]. The protocol, research method, and collected data have been checked and overseen by the Research Working Group (RWG), which is headed by Carol Narra, Philippine Dangerous Drugs Abuse and Prevention and Treatment Program (DDAPTP) and is composed by both Japanese and Philippine researchers. The RWG is also responsible for auditing core trial processes.

2.2. Study setting

The INTREPRET will be introduced to three DOH-operated TRCs. They were selected to maintain the representativeness in terms of the characteristics of the patient and facility, and thus keep the external validity of the study.

2.3. Participants enrollment and allocation

The participants are recruited from newly admitted patients at three TRCs for approximately three years from February, 2000. Those who meet the eligibility criteria get selected as possible participants for the study. After obtaining informed consent, they are to be assigned randomly either to the intervention group or to the control group. During the intervention phase, the patients in the intervention group will receive

the INTREPRET, while those in the control group will receive the existing TC-based treatment service (TAU: treatment as usual).

The randomization of the eligible patients is to be done by the independent research assistants who are not part of the TRC administration. When a new eligible patient is admitted to TRCs, he is randomly assigned to either of the groups using a pre-determined computer-generated random number table. The randomization table is concealed by the research assistants in their office until the end of the trial.

The blinding of participants in terms of innervations they receive may be impossible due to the nature of the intervention. However, research assistants who are responsible for recruit of possible participants and data collection are adequately blinded.

2.4. Eligibility criteria

The inclusion criteria for this study are as follows:

1. Residential patients newly admitted to one of the three pilot TRCs
2. Male
3. 18 years of age or older
4. Ever used methamphetamine

In addition, the following exclusion criteria are applied:

1. Those who are not capable of participating in group sessions
2. Those who cannot communicate in Tagalog
3. Those who have criminal records other than the possession of illegal drugs, possession of drug paraphernalia, or use of illegal drugs
4. Those with severe medical conditions
5. Those who are not considered eligible by researchers

The patients in the intervention group are separated from those in the control group (and those not participating in the study) by residing in a dormitory designated just for the group to avoid possible contamination. They are also instructed not to disclose treatment materials to non-participants. No specific dormitories are to be designated for the control group and will reside in non-intervention group dormitories together with those not participating in the study.

2.5. Sample size calculation

Based on recently published findings from the systematic review which includes studies with a similar design [7], this study considers a minimum detectable effect of 0.23 and a population standard deviation of 0.42. With a significance level of 0.05 and a power of 0.95, a sample size of 88 participants per group (or 176 patients in total) would become needed to test the causal impact of the intervention.

Moreover, judging from our preparatory field studies, more than a half of the participants may drop out of the study by not showing up for the follow-up interviews in three months after discharge. Given the coverage rate of 44%, the final required sample size needs adjusting to 200 patients per group (or 400 patients in total) to achieve a sample size of 88 patients per group (or 176 patients in total).

2.6. Intervention

The original Matrix Model was translated into the Tagalog language and local researchers and practitioners were checked the translation multiple times. Also, the contents were tailored considering the cultural and social background of the Philippines and specific treatment needs of Philippine drug users and was also modified to be conducted in residential TRC settings.

The INTREPRET is composed by the five components; CBT sessions, CBT-review sessions, psycho-education sessions, social support sessions, and self-help group meetings. To implement these 5 components of the INTREPRET, the following materials were developed:

1. Patient's Workbook
2. Slides for psycho-education sessions
3. Flipcharts for social support sessions

During the intervention, the patients in the intervention group will receive the INTREPRET by participating in: 3 sessions of CBT; 1 session of CBT-review; 1 session of psycho-education; 2 sessions of social support; and, 1 session of self-help group meeting, per week. All sessions are provided in groups. Each session is for 60 minutes. At the shortest, the INTREPRET can be completed in 26 weeks or 6 months. Other than these CBT intervention, participants will join other TC-based activities such as physical activities and religious meetings.

The patients in the control group will receive the TAU based on the TC approach. Typically, patients participate in a variety of daily activities designed by TRCs including therapeutic meeting, physical activities, education, and religious meeting, and house-keeping activities [17].

2.7. Therapists

The therapists for the both groups are psychologists or social workers. The psychologists who provide the INREPRET sessions to the intervention group will receive specifically developed 5-day training for this study, consisting of lectures and hands-on group sessions on: 1) INTREPRET administration; 2) facilitation standards; 3) CBT; and, 4) motivational interviewing followed by three-month dry run sessions. The trainers were experienced psychologists and psychiatrists, who have had participated in the Matrix training in the US in 2017 and 2018. Moreover, treatment integrity will be monitored by trainers during the dry run period using a fidelity checklist which were developed prior to the trial.

2.8. Data collection and research instruments

Outcome data will be collected at three phases; pre-treatment, post-treatment, and 3-month follow-up (Figure 1). As a means of collecting data on the primary outcome (i.e., drug use), the urine testing for stimulant is to be implemented only at the follow-up. In addition, self-administered questionnaires are to be conducted to collect outcome data on self-reported stimulant use. The self-administered questionnaires are also to be used to measure the patient's demographics and psycho-social variables. For the measurement of psychological variables, several psychometric scales will be employed in baseline, pre-discharge, and follow-up, as follows;

1) Drug Abuse Screening Test 20 (DAST 20) to screen drug related disorders [18].

2) Addiction Severity Index-Self Report (ASI-SR) to evaluate severity of drug-related problems [19].

3) Simulant Relapse Risk Scale (SRRS) to evaluate relapse risk of stimulants use [20].

4) Visual Analogue Scale (VAS) for Craving to evaluate subjective magnitude of drug craving [21].

5) Coping Behaviours Inventory-Drug (CBI-Drug) to evaluate coping behaviors related to drug use [22].

6) Brief Coping Orientation to Problems Experienced (Brief COPE) to evaluate general coping repertoire [23].

7) World Health Organization Five Well-being Index (WHO-5 Well-being Index) to evaluate overall well-being [24].

8) Five Level EQ-5D (EQ-5D-5L) to evaluate health-related quality of life including mobility, self-care, usual activities, pain/discomfort and anxiety/depression [25].

9) Beck Depression Inventory II (BDI-II) to screen depression [26].

10) Perceptions of Care (PoC) to evaluate self-report care satisfaction [27].

DAST 20, SRRS, and VAS for Craving had been translated into Tagalog and validated during a separate study conducted earlier. The other study tools have been translated into Tagalog by professional translators, reviewed by local addiction experts on several occasions. The revised study tools have further been reviewed by several addiction experts before they were finalized.

In order to ensure the anonymity and privacy of the participants, all the data will be de-identified and managed by codes at the data entry and analysis stages. Data will be anonymized in a linkable fashion; a separate table that links the participants' codes and names will be developed and kept in a safe that can be opened solely by designated personnel.

2.9. Data analysis

To estimate the causal impact of providing residential treatment on outcomes, the following two types of regression equations are to be estimated:

1) For the primary outcome indicator of the urine testing, the regression model (1) is estimated to test if there is a statistically significant difference in means between the intervention and control groups:

$$Y_{ij} = \alpha + \beta T_i + \theta X_i + v_j + \omega_{ij} \quad (1)$$

where Y_{ij} is the urine test result of patient i at TRC j, is a constant giving the value of the urine test result for the control group, T_i is the treatment dummy, X_i is the set of patient characteristics to be controlled for, such as age and education, v_j is a TRC-level error term, and w_{ij} is an individual error term.

This study estimates the coefficient on the treatment dummy (β) that shows the between-group difference. Since the urine test has a binary result, the log odds of the outcome are to be estimated as a linear combination of the independent variables using a logistic regression (i.e., logit (Y_{ij})), instead of using a linear regression.

2) For the secondary outcome indicators of the psychometric tests, which are to be measured both at baseline and follow-up, the regression model with an interaction term (2) is estimated to calculate a difference-in-difference (DD) estimate that relies on a comparison of the intervention and control groups before and after the intervention [28]:

$$Y_{ijt} = \alpha + \beta T_{i1} t + \rho T_{i1} + \gamma t + \theta X_i + v_{jt} + \omega_{ijt} \quad (2)$$

where Y_{ijt} is the psychometric test result of patient i at TRC j at time t, α is a constant giving the average value of the psychometric test result for the comparison group at time t_0 (baseline), T_{i1} is the treatment dummy, t is the time dummy, x_i is the set of patient characteristics to be controlled for, v_j is a TRC-level error term, and w_{ij} is an individual error term.

The study estimates the coefficient (β) on the interaction between the treatment dummy (T_{i1}) and the time dummy (t) that gives the average DD effect of the intervention. In addition to this interaction term, the variables T_{i1} and t are included separately to pick up any separate mean effects of time as well as the effect of being targeted versus not being targeted.

2.10. Patient and public involvement

Psychometric tools for outcome measurement were pretested with approximately 40 patients at two TRCs. Feedback comments from those patients and the staff members who observed the pretest sessions were obtained. The treatment programs were also implemented prior to the commencement of the study in all of the study sites and feedback from the patients were obtained. These comments were used for development of the tools and programs, and administration of the study.

Ethics And Dissemination

This study does not expect that participants suffer from any adverse effects, either physically or mentally. To our knowledge, the existing studies with a similar intervention have not reported any serious adverse effects. In case of any significant negative events, the intervention would be ceased or modified.

The following measures are to be taken to uphold high research ethical standards:

1. Potential participants will be given summary of the study and a consent form. The consent form is signed and dated by participants prior to their study participation.
2. The participants are duly informed that they can withdraw from the study anytime without any negative consequence.
3. Participants will be compensated for inconvenience and expense when they attend the follow-up interview. Specifically, participants showing up and cooperating in the follow-up will receive as honorarium 500 pesos, whereas those answering the interview through telephone will receive 200 pesos.
4. All patient data are treated as confidential. Any personally identifiable information is removed from datasets in a linkable anonymizing manner. Each participant is given a unique study identification number, which is linked to his personal information and the list for a linkable anonymizing is kept in a cabinet under lock and key in the project office.
5. The consent forms and the questionnaire forms will be kept in a lockable cabinet of at the Department of Health for five years after completing all the data collection. After the storage period, all the sheets will be shred and disposed.
6. This study was approved by Single Joint Research Ethics Board of the Department of Health, Republic of the Philippines (SJREB-2019-27) and the University of Tsukuba Faculty of Human Sciences Ethics Committee (T2019-70).
7. No researches have any competing interests concerning the current study.

The results of the study are planned to be disseminated to a wide range of audiences through presentations and publications afterwards. The brief result will be reported on clinicaltrials.org.

Any modifications to the protocol which may impact on the conduct of the study, potential benefit of the patient or may affect patient safety, including changes of study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendment will be agreed upon by RWG and approved by the Ethics Committee prior to implementation.

Abbreviations

INTREPRET Intensive Treatment and Rehabilitation Program for Residential Treatment and Rehabilitation Centers

JICA：Japan International Cooperation Agency

CBT：cognitive-behavioral therapy

TC：Therapeutic community

Declarations

Ethics approval and consent to participate: This study was approved by Single Joint Research Ethics Board of the Department of Health, Republic of the Philippines (SJREB-2019-27) and the University of Tsukuba Faculty of Human Sciences Ethics Committee (T2019-70). 1). Potential participants will be given summary of the study and a consent form. The consent form is signed and dated by participants prior to their study participation.

Consent for publication: Not Applicable

Availability of data and materials: The datasets generated and/or analysed during the current study are available in the Harvard Dataverse repository, https://dataverse.harvard.edu/dataset.xhtml?persistentId=doi:10.7910/DVN/CPRRYA

The registration number: 10.7910/DVN/CPRRYA the Data of registration: 9th January 2021

Competing interests: All researchers have no competing interests.

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Authors' contributions: TH was involved in designing and writing the protocol, supervising the whole process of the study; TB was involved in designing the protocol and writing the draft; TS reviewed the protocol; SK was involved in designing and writing the draft, administrating study process; All authors contributed to refinement of the study protocol and approved the final manuscript.

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Trial status:

The INTREPRET protocol is currently on version 1.0. Recruiting of this trial was planned to commence on March 1, 2020, and run through to the anticipated completion of the trial in mid-2022. However, due to the pandemic of the COVID-19, the trial is currently suspended.

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Figures

	STUDY PERIOD				
	Enrollment	Allocation	Post-	Post-	Follow-up
TIMEPOINT	$-t_1$	0	t_1	t_2	3 months
ENROLMENT:	X				
Eligibility screen	X				
Informed consent	X				
Randomization	X				
INTERVENTIONS:					
INTREPERT			X		
TAU			X		
ASSESSMENTS:					
Drug use:					
Self-report		X			X
Urine test		X			X
Psychological:					
DAST-20		X			X
ASI-SR		X			X
SRRS		X		X	X
VAS		X		X	X
CBI-Drug		X			X
Brief COPE		X			X
WHO-5 Well-being Inde		X		X	X
EQ-5D-5L		X		X	X
BDI-II		X		X	X
PoC				X	

Figure 1

Schedule of enrolment, interventions, and assessments

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SPIRITchecklist.docx
- StudyProtocol20191030.pdf