CHAPTER III: METHODOLOGY

3.1 Introduction

This chapter introduces the study methodology. The study design, study population, location, sample size, study inclusion and exclusion criteria, sampling procedure, data collection techniques, study instruments and data analysis are all clearly described in this chapter.

3.2 Study Design

This study utilizes quantitative research designs by applying data to make statistical inferences about the population of interest. In this study, data collection survey of a population will be implemented at one point in time or cross-sectional design. It is useful for describing a population or the relationship among variables within a sample (Miller et al., 2010). In addition, besides measuring the participant's outcome and exposure at the same time, the investigator can also investigate the association between dependent and independent variables and estimate the prevalence of the outcome in the survey (Setia, 2016). Moreover, a cross sectional study is significant to assess the prevalence of a disease in a population (Munnangi & Boktor, 2021) and understand the determinant factor of health and describe the features of a population (Wang & Cheng, 2020).

The scope and objectives in this study is appropriate with cross sectional study design. In addition, Vicknasingam et al. (2009) concluded that findings from cross-sectional study is usually be able to provide brief and reliable base information about a specific emerging problem among population of illegal drug use. Contrast with other

types of observational studies, cross-sectional studies do not need to follow up individuals over time and usually inexpensive and easy to conduct in the study ground (Setia, 2016). In advance, cross sectional study is very useful in establishing preliminary evidence in planning a future more advanced study (Wang & Chen, 2009).

3.3 Study Population

All the respondents in this study were former opiate users who are currently active involve in Methadone Maintenance Treatment (MMT) program. According to Ministry of Health Malaysia (MOH), about 49,502 people have registered for MMT program until 2019 (Pharmacy Programme Statistics Report, 2019). Out of this number, only 16,914 people were actively involved in MMT program throughout Malaysia. Meanwhile, Unit Kawalan Penyakit AIDS/STD Jabatan Kesihatan Negeri Kelantan (JKNK) reported that about 3,145 people have registered for MMT program in Kelantan until October 2021. Out of this figure, only 718 clients were actively received methadone treatment in Kelantan

3.4 Study Location

The study will be conducted in government MMT facilities in Kelantan state. Kelantan is located in the northeast of Peninsular Malaysia and bounded with Thailand in the north. Majority of its residents are involved in the agricultural and business sectors. The total of MMT facilities in Kelantan that provide medical assisted therapy to drug opiate users is 53 MMT facilities at primary care setting and 8 MMT facilities at hospitals. All MMT facilities scattered throughout 10 districts in Kelantan. Each MMT facility conducted by dedicated healthcare team among medical practitioners,

pharmacists and medical assistants. Table 3.1 showed the lists of healthcare and hospital that involved in the study:

Table 3.1 List of MMT Facilities Involved in the Study

DISTRICTS	HEALTH FACILITIES KLINIK KESIHATAN (KK)
Kota Bharu	Hospital Raja Perempuan Zainab II (HRPZ II)
	KK Bandar Kota Bharu
	KK Pengkalan Chepa
	KK Wakaf Che Yeh
	KK Badang
Tumpat	KK Wakaf Bharu
	KK Tumpat
	KK Pengkalan Kubor
	KK Bunohan
	KK Sungai Pinang
Pasir Mas	KK Bandar Pasir Mas
	KK Tendong
	KK Rantau Panjang
Tanah Merah	KK Kemahang
Bachok	KK Bachok
	KK Beris Kubor Besar
	KK Gunong
Pasir Puteh	Hospital Tengku Anis
	KK Selising
	KK Cherang Ruku

Kuala Krai	KKB Kuala Krai
	KK Manek Urai
Gua Musang	KKB Gua Musang
	KK Chiku 3
Jeli	KK Jeli
	KK Ayer Lanas
Machang	KK Labok
	KK Batu 30

KK = Klinik Kesihatan

3.5 Sample Size

The sample size for the actual study is calculated based on the table for determining sample size from a given population (Krejcie & Morgan, 1970). Unit Kawalan Penyakit AIDS/STD Jabatan Kesihatan Negeri Kelantan (JKNK) reported that about 3,145 people have registered for MMT program in Kelantan until October 2021. Out of this figure, only 718 clients were actively received methadone treatment in Kelantan. The sample size determination table is derivative from the sample size calculation which expressed as below equation (Krejcie and Morgan, 1970). The Krejcie and Morgan's sample size calculation was based on $p = 0.05$ where the probability of committing type error is less than 5 % or $p < 0.05$.

s=X2 NP(1-P) ± d2 (N—])+X2 P(1—P)

where,

s = required sample size.

X^2 = the table value of chi-square for 1 degree of freedom at the desired confidence level (0.05 = 3.841).

N = the population size.

P = the population proportion (assumed to be 0.50 since this would provide the maximum sample size.

d = the degree of accuracy expressed as proportion (0.05)

Since the sampling frame for methadone users at Kelantan were known. According to Krejcie and Morgan's sample size determination table, the sample size representative for this study is 275 samples. Allowing for 10% dropout, a final sample size is n=300.

3.6 Study Inclusion and Exclusion Criteria

The inclusion criteria for the study include; 1) 18 years and above, 2) currently involve as active clients in Methadone Maintenance Treatment (MMT) program and 3) being in MMT program of more than 3 months. Those who had severe psychological problems (schizophrenia and bipolar disorder) and reluctant to give written-informed consent were excluded from the study.

3.7 Study Sampling

A stratified random sampling design will be adopted in this study. Currently, there are only 60 MMT clinics in 10 districts of Kelantan. Majority clients register

MMT programme at local facilities and nearby with their home. The population mobility of MMT clients is low and the population is concentrated, so the cumulative number of clients in MMT clinic can reflect the prevalence of ATS misuse in the clinic. Therefore, first of all, we divided 300 samples according to geographical location of districts. All districts should obtain 20-30 samples and then randomly selected 2-5 MMT clinics as our research sites for each district. Finally, in each selected MMT clinics, we invited patients who met the inclusion criteria to join the study.

3.8 Data Collection Procedure

The study data will be collected from April to June 2022 through face-to-face interviews. The survey of semi-structured questionnaire will be administered by investigator. The surveys will be held at MMT clinics and conducted in quiet, privacy and convenient. Respondents will response solely based on their self-report. Self-report is regarded as acceptable despite its limitations because of the practical difficulty in using a more accurate measure to detect ATS misuse among MMT clients (Miller et al., 2010). Self-report is one of the most widely used methods of collecting information regarding individuals' health status and utilisation of healthcare services (Short et al., 2009). A study by Napper et al. (2010) showed self-report is a reliable and valid approach that can be used to determine prevalence of ATS use.

A four-part questionnaire will be used to perform the investigation. The first part covered socio-demographic characteristics, second part is concurrent drug use information, third part is Multidimensional Scale of Perceived Social Support (MSPSS) and last part is BRIEF COPE-M.

3.9 Study Instrument

The Multidimensional Scale of Perceived Social Support (MSPSS) will be used to measure the perceived social support received by the participants. It is a self-rating instrument which contains 12 items that measure the subjective perception of social support from family, friends, and significant others. Each subscale has 4 items, and each item is rated on a 7-point Likert-type scale ranging from very strongly disagree (1 point) to very strongly agree (7 points). A total score of 50 or more represents good perceived social support. Published data have shown that the MSPSS has high internal consistency reliability (Cronbach's α: 0.92) and excellent factorial validity (Eker & Arkar, 1995). Similarly, the Malay version of the MSPSS has shown to have good internal consistency and validity with Cronbach α of 0.89 (Guan et al., 2010).

Coping strategies used by patients attending MMT clinic will be assessed using the Brief COPE. This questionnaire consists of questions on a 4-point Likert scale ("I haven't been doing this at all," "I've been doing this a little bit," "I've been doing this a medium amount," and "I've been doing this a lot"), and assesses 14 dimensions of coping strategies. Each of the 14 scales is comprised of 2 items and total scores on each scale ranges from a minimum of 2 and maximum of 8. Higher scores indicate increased utilization of that specific coping strategy. Brief COPE categorizes the 14 dimensions of coping into active coping, planning, positive reframing, acceptance, humor, religion, using emotional support, and using instrumental support whereas maladaptive coping includes self-distraction, denial, venting negative emotion, substance use, behavioral disengagement, and self-blame. Yusoff et al. (2010) found the Malay Version of brief COPE to be reliable and valid.

There is currently a lack of consensus about the theoretical or empirical foundations for grouping the multiple coping strategies into more overreaching categories of coping (Nahlen et al., 2015). As the Brief COPE does not yield an overall score, researchers often use Exploratory Factor Analysis with principles component to create higher order factors based on their own data as suggested by Carver et al. (1989). There is a variation in latent factor structures among published literature using the Brief COPE (Krageloh, 2011). Some practical, as well as conceptual, issues such as several analyses, fragmentation of results and overlapping coping strategies, in the use of data from Brief COPE may arise due to the large number of subscales in this instrument.

To address such issues and in order to facilitate analysis of coping strategies, some studies have attempted to arrive at higher factors encompassing aggregates of several coping strategies. Based on either exploratory factor analysis, or principal component analysis, Brief COPE has been suggested to consist of two (Bean et al., 2019) and three factors (Paukert et al., 2009). Higher order factors have also been proposed, based on the structure of the COPE where Brief COPE has been suggested to consist of four second order factors (Nahlen & Sobbonchi, 2010).

3.10 Data Analysis

All the study data will be analysed with the Statistical Package for Social Sciences (SPSS) software version 27. Two different data analysis techniques will be applied in this study. First, descriptive statistics are used to describe the study data. Descriptive statistics are used to summarize characteristics of the study respondents by expressing the results as mean ± standard deviation (SD) or percentage. The prevalence

of concurrent drug use among MMT clients, as well as their respective 95% confidence intervals (CI) will be presented.

Second, quantitative analysis is also computed to further determine the relationship between the dependent and independent variables. The research objectives and data analysis were shown in Table 3.2.

Table 3.2 Research Objectives and Data Analysis

No	Research Objectives	Data Analysis
1	What is the prevalence of concurrent drug use of MMT clients at Kelantan?	Descriptive Statistic
2	What is the level of social support of MMT clients at Kelantan?	Descriptive Statistic
3	What is the level of coping skills of MMT clients at Kelantan?	Descriptive Statistic
4	Is there any significant mean difference of social support based on employment and marital status and among MMT clients at Kelantan?	*t*-test and one way ANOVA
5	Is there any significant mean difference coping skills based on education level and accommodation status among MMT clients at Kelantan?	One way ANOVA
6	Is there any significant mean difference between social support and MMT clients with and without concurrent drug use at Kelantan?	t-test
7	Is there any significant mean difference between coping strategies and MMT clients with and without concurrent drug use at Kelantan?	t-test

8	Is there any significant correlation between social support and coping skills among MMT clients at Kelantan?	Pearson Correlation
9	Is there any significant association between social support, coping skills and concurrent drug use among MMT clients at Kelantan?	Logistic Regression

3.11 Ethics

The study protocol has been reviewed and approved by the National Medical Research Register (NMRR) and Medical Research and Ethics Committee (MREC). A copy of the ethics approval certificate, copy of the Study Information and Subjects Consent form, as well as study questionnaire are attached in APPENDIX A, APPENDIX B and APPENDIX C. All the respondents in this study gave their written-informed consent. Letter of Ethical Approval letter from Jabatan Kesihatan Negeri Kelantan (JKNK) is attached in APPENDIX E.

3.12 Conclusion

The study methods have been thoroughly described in this chapter. The next chapter will disclose the study finding.