THE PREVALENCE OF RELAPSE AND ITS ASSOCIATED FACTORS AMONG SMOKERS ATTENDING KLINIK RAWATAN KELUARGA, HOSPITAL UNIVERSITI SAINS MALAYSIA

by

DR. NORIHAN ABU BAKAR

Dissertation Submitted In
Partial Fulfillment Of The
Requirements For The Degree Of
Master Of Medicine
(Family Medicine)

UNIVERSITI SAINS MALAYSIA
2011

ACKNOWLEDGEMENTS

I must praise to Allah SWT; the Almighty Who has given the strength and guidance to me from the beginning of the research preparation till the end. I would also like to express my special appreciation to those who have helped and given their priceless contributions:

1. My supervisor, Dr Harmy Mohd Yusoff, Head of Department and lecturer of Family Medicine Department for the time, idea and critics
2. My co-supervisor, Dr Adibah Hanim Ismail, lecturer of Family Medicine for her continuous support
3. Dr Norhayati Mohd Noor, lecturer of Family Medicine for helping in the statistical analysis
4. The Research and Ethical Committee of school of Medical Sciences, USM for the permission for me to conduct the study
5. Miss Siti Aminah Yusof, my research assistant who was helping for the data collection
6. Staffs in Klinik Kesihatan Gunong for allowing and helping me to conduct the pilot study there
7. All lecturers and staffs in the Family Medicine Department for their compassionate support

And last but not least, to my beloved husband, children and family for all the prayers, support and patient throughout my post graduation studies.

TABLE OF CONTENTS

Chapter Four : Results

Chapter Five: Discussion

LIST OF TABLES AND FIGURES

LIST OF APPENDICES

ABBREVIATIONS

FTND	Fagerstrom Test for Nicotine Depedence
HUSM	Hospital Universiti Sains Malaysia
KRK	Klinik Rawatan Keluarga
MMWR	Morbidity and Mortality Weekly Review
NHMS	National Health and Morbidity Survey
QSC	Quit Smoking Clinic
WHO	World Health Organization

ABSTRAK

PREVALENS MEROKOK SEMULA DI KALANGAN PEROKOK DAN FAKTOR-FAKTOR YANG BERKAITAN DENGANNYA DI KLINIK RAWATAN KELUARGA, HOSPITAL UNIVERSITI SAINS MALAYSIA

Objektif: Kajian ini dibuat untuk menentukan prevalens perokok yang merokok semula dalam kalangan perokok dan faktor-faktor berkaitan dengannya di Klinik Rawatan Keluarga, HUSM.

Metodologi: Kajian ini merupakan kajian hirisan lintang. Seramai 294 responden telah terpilih bagi menjawab soalan-soalan menggunakan borang soal-selidik pada bulan Jun sehingga Ogos 2010. Maklumat tentang sosio-demografik dan faktor-faktor berkaitan direkodkan menggunakan borang tersebut.

Keputusan: Seramai 283 orang reponden telah berjaya melengkapkan borang soal selidik tersebut. Hal ini menunjukkan maklum balas kajian ini adalah sebanyak 96.3%.Hasil kajian mendapati bahawa, prevalens perokok yang merokok semula adalah tinggi iaitu 59.4%. Faktor-faktor yang berasosiasi dengannya adalah umur kurang daripada 40 tahun, status perkahwinan, skor Fagerstrom, tempoh merokok dan tekanan hidup.

Kesimpulan: Kajian ini menunjukkan kegagalan berhenti merokok dalam kalangan perokok yang cuba berhenti merokok adalah tinggi. Oleh itu, perokok yang menghadiri klinik merokok yang mempunyai faktor-faktor di atas memerlukan perhatian dan sokongan yang lebih serius bagi memastikan kejayaan mereka untuk berhenti merokok.

ABSTRACT

THE PREVALENCE OF RELAPSE AND ITS ASSOCIATED FACTORS AMONG SMOKERS ATTENDING KLINIK RAWATAN KELUARGA, HOSPITAL UNIVERSITI SAINS MALAYSIA

Objectives : To determine the prevalence of relapse and its associated factors among smokers at Klinik Rawatan Keluarga, HUSM.

Method : This is a cross sectional study. Two hundred and ninety-four respondents agreed to participate in the study from June until August 2010. The socio-demographic and associated risk factors were recorded in the data questionnaires.

Result : A total of 283 respondents managed to complete the questionnaires. There was 96.3% response rate. The proportion of smokers who relapsed was 59.4% (n=168). The significant associated factors to relapse were age less than 40 years old, marital status , Fagerstrom score, duration of smoking and stressful life event.

Conclusion: The prevalence of relapsed is high which is comparative to many other studies. For smokers who are attending quit smoking clinics, special attention should be given to those with the associated factors to make our quit smoking clinic more successful.

CHAPTER ONE

INTRODUCTION

Tobacco is one of the major cause of death in the world and claimed 5 million of deaths each year(WHO, 2011) and most of the death are from the middle and lower income countries(WHO, 2009).

The morbidity and the mortality associated with tobacco is changing from the developed country to the developing country including Malaysia(NHMS, 2006). While the developed countries demonstrated declining trend of smoking prevalence, most of the developing countries are showing differently. In the United States, the prevalence of current smoker has dropped from 24.1% in 1998 to 20.6% in 2008(MMWR, 2009). In a population survey in Italy, from 1986-87, 1989-90, there were declined of smoking among males(Cesana *et al.*, 1995). The same situation has also been observed in Sweden(Wersall and Eklund, 1998).

1.1 Smoking In Malaysia

It was encouraging to see the downward trend of current smokers in the third National Health morbidity Survey 2006 (NHMS 6) among adult smoker. However, the result among younger smoker was not favourable despite all the anti-smoking campaign. Smoking prevalence among older teenagers (18-19 years old) rose from 17.6% in 1996 to 22.1% in 2006 and young adults (20-24 years of age), from 23% in 1996 to 27% in 2006(NHMS, 2006). In one survey, the prevalence of adolescent smokers age 13 to 17 years was about 3% with additional 10-12% reported as experimental smokers(Hammond, 2008). Global Youth Tobacco Survey 2003(GYTS) among Malaysian adolescents current smoker aged between 13 to 15 years old reported as

19.9% (Manimaran, 2003) while NHMS 3 showed a lower figure, 6.1%. Among adult, Kelantan showed the highest prevalence of current smoker (7.3%)(NHMS, 2006) in Malaysia.

1.2 Smoking Cessation Attempt

Substance abuse such as tobacco, alcohol or illicit drug used cessation is a unique process that involve multiple attempts before a long term abstinence is achieved. Due to increased of stop smoking campaign, health awareness and more expensive tobacco tax, majority smokers wish to quit.

National Health Morbidity Survey in 2006 reported that as high as 70.6% of current smoker attempted to quit(NHMS, 2006). Other survey; GYTS reported 88.3% among adolescent aged 13 to 15 years old(Manimaran, 2003) had attempted to quit. Average of the number of quitting attempt is 2.1 times in the past 1 year(NHMS, 2006). Meanwhile, the intention to quit smoking within next 6 months is 71.1%. One in ten adults claimed to be an ex smoker(NHMS, 2006). The ATTEMPT study was a longitudinal, prospective, web-based study; followed up 3645 respondents who expressed their willingness to quit smoking from Canada, France, United Kingdom and United States for 18 months in 2004(Zhou *et al.*, 2009). The objective of the study was to assess predictor factors to quitting attempt and relapse. From this study, 74% of eligible subjects who intended to stop smoking in the next 3 months made a quit attempt during the next 18 months(Zhou *et al.*, 2009). In this study also found that, subjects who made more attempts in the past were more likely to make a new attempt compared to those who made fewer attempt and those who failed an attempt 3 months prior to the study were more than twice likely to make a new attempt than subjects who had no recent attempt(Zhou *et al.*, 2009).

In a cohort study by Himowitz et al, 13,415 smokers were followed up for 5 years (1988-1993) to identify predictor factors of smoking cessation. After 5 years, 67% smokers reported had made at least 1 quitting attempt but only 33% of them managed to quit successfully(Hymowitz *et al.*, 1997).

The National Tobacco Programme has outlined that one of its objective is to increase the number of smokers giving up smoking(Zain, 2007). Quit smoking clinic at the government hospitals and clinic was developed with Hospital Ipoh became the pioneer in 1998(No date). Nowadays, there are about 300 quit smoking clinics nationwide(No date). A study by Wee et al at 5 quit smoking clinic showed that the abstinence rate is about 35% in 3 months time(Wee *et al.*, 2010).

Relapse in general means a current smoker reported to smoke regularly again after a period of abstinence. It can be as short as one day or as long as many years. There were numerous studies done to look into factors of smoking relapse, either while the smokers still in their quitting attempt period or after they have stopped smoking for more than 6 months and being considered as former smokers. Attempt to stop smoking is a dynamic process and smokers are prone to relapse at any time even after so many years due to various factors. People are interested to know factors that cause smoking relapse in relation to time.

In this study, relapsed means current smokers reported to smoke again after a period of abstinence for the minimum of 1 day. Smokers are considered successful to stop smoking when they manage to achieve abstinence for more than 6 months. Factors that contributed to smoking relapse after 6 months may not be similar.

1.3 Factors To Success

Most of the studies look into the factors of success quit smoking among smokers. Common reasons given for quitting were concern over health (91%)(Hymowitz *et al.*, 1997), expense (60%)(Hymowitz *et al.*, 1997), concern about exposing others to second hand smoker (56%)(Hymowitz *et al.*, 1997) and wanting to set a good example for others (55%)(Hymowitz *et al.*, 1997).

Statistically significant predictors of smoking cessation include male gander(Hymowitz *et al.*, 1997, Nides *et al.*, 1995, Ferguson *et al.*, 2003, Wetter *et al.*, 1999, Gourlay *et al.*, 1994), older age(Li *et al.*, 2010, Richmond *et al.*, 1993, Yu *et al.*, 2004, Gourlay *et al.*, 1994, MMWR, 2009, Kabat and Wynder, 1987), higher income (Herd *et al.*, 2009, Matheny and Weatherman, 1998, Richmond *et al.*, 1993, Lam *et al.*, 2005),higher education(Nides *et al.*, 1995, Rohren *et al.*, 1994), retired/unemployed(Yu *et al.*, 2004), married(Matheny and Weatherman, 1998, Senore *et al.*, 1998, Gourlay *et al.*, 1994, McDermott *et al.*, 2009), less frequent alcohol intake(Herd *et al.*, 2009), lower levels of daily cigarette consumption(Herd *et al.*, 2009, Li *et al.*, 2010), longer time to first cigarette in the morning(Herd *et al.*, 2009),lower levels of nicotine dependence(Rohren *et al.*, 1994, Richmond *et al.*, 1993, Stapleton *et al.*, 1995, Kazlowski, 1994), the use of premium cigarettes(Herd *et al.*, 2009), initiation of smoking after age 20(Herd *et al.*, 2009), history of past quit attempts(Herd *et al.*, 2009, Norregaard *et al.*, 1993), strong desire to stop smoking(Herd *et al.*, 2009),the absence of other smokers in the household(Herd *et al.*, 2009, Matheny and Weatherman, 1998, Richmond *et al.*, 1993), longer abstinence period(Li *et al.*, 2010, Ferguson *et al.*, 2003, Stapleton *et al.*, 1995), brief counselling and stop smoking advice(Milch *et al.*, 2004, Ferreira-Borges, 2005, Law and Tang,

1995) and used nicotine replacement therapy(Lam *et al.*, 2005, Abdullah *et al.*, 2006, Law and Tang, 1995).

There are still lacking in local research regarding smoking in Malaysia. There were two studies done to identify the associated factors to success quitting attempt in Malaysia(Wee *et al.*, 2010, Li *et al.*, 2010).The study by Wee et al(2010), which was designed prospectively among 198 smokers attending 5 stop smoking clinics in Malaysia reported that abstinent at 3 months were associated with older age, married, intended abrupt quitting rather than gradual, Chinese, unhappy to be a smoker, strongly motivated to quit, confident to quit and wanted to quit for good(Wee *et al.*, 2010). Nicotine level (assessed by Fagerstrom Test for Nicotine Dependence) was not a predicting factor to smoking cessation while relapsed was significantly due to want to cope with stress and to help socialize.

Another study by Li et al(2010) showed that smoking less cigarettes per day, higher levels of self-efficacy, and more immediate quitting intentions were predictive of both making a quit attempt and continue quitting. History of shorter stop smoking attempts and more concern about health were only predictive of making an attempt, while past bstinence for at least 6 months and older age were associated with smoking abstinence(Li *et al.*, 2010).

Thus, more studies are needed to identify biological and psychosocial factors that associated with success or fail to stop smoking among local smokers.

1.4 Associated factors to relapse

It is important to know why majority of them failed. Attention to these factors is necessary as part of the guidance for smoking cessation program at our health clinics. The objective of this study is to look at the associated factors which were studied by researches mainly done at western countries and from my observation that contribute to relapse among currents local smokers. Below are factors that contributed to relapse.

1.4.1 Socio demographic Factors

a. Age

Most studies reported older age is a predictor to abstinence(Wee *et al.*, 2010, Richmond *et al.*, 1993, Gourlay *et al.*, 1994, Lam *et al.*, 2005, Yu *et al.*, 2004, Hymowitz *et al.*, 1997). However, a study by Milch et al (2004) on brief interventions on screening for smoking, physician advice and stop smoking rate found that quitters were younger(Milch *et al.*, 2004). To the best of our knowledge, no study is done to see the association of age and smoking relapse.

b. Gender

Majority studies have shown that male gender is one of the predictors of smoking cessation(Hymowitz *et al.*, 1997, Ferguson *et al.*, 2003, Senore *et al.*, 1998). However, there were conflicting findings in gender. Studies by Mckee et all(2002) and Ward et al(1997) showed that women were more likely to fail quit smoking attempt(McKee *et al.*, 2003, Ward *et al.*, 1997). On the other hand, Westmaas et al

(2005) and Matheny et al reported that there was no gender difference in quitting rate(Westmaas and Langsam, 2005, Matheny and Weatherman, 1998)

c. Ethnicity

Smoking is more prevalent among Malay. For current smokers, the highest prevalence were reported among Malay and other Bumiputera i.e. 24.0% and 24.8% respectively(NHMS, 2006). Similar finding was reported by Wee et al(2010)(Wee *et al.*, 2010).

d. Marital Status

Many studies have examined the association of marital status and smoking cessation outcome. Senore et al (1998) suggested that smokers, married or living common-law, were significantly likely to quit than those who were single, divorced or widowed(Senore *et al.*, 1998). Mc Dermott et al (2009) found that being married is a protective factor from being relapse(McDermott *et al.*, 2009) meanwhile Matheny et al (1998) reported that married and never married were associated with smoking abstinence(Matheny and Weatherman, 1998).

e. Socio-economy status

This factor is determined by income and educational level. Low socio-economic status(Hymowitz *et al.*, 1997, Richmond *et al.*, 1993, Yang *et al.*, 2006, Paavola *et al.*, 2004) and educational level(Wetter *et al.*, 2005, Paavola *et al.*, 2004, McDermott *et al.*, 2009) were significant factors to smoking cessation outcome in many studies . Less smoking decline among low educational status from 1985 – 2000 was observe in some European countries(K Giskes and K Judge, 2004). Findings from the

International Tobacco Control (ITC) in 4 countries survey (US, Canada, UK and Australia) found that smokers with financial stress were more likely to quit but less likely to make quitting attempt and lower probability of abstinence at follow up(Herd *et al.*, 2009).

f. Occupation

Studies have shown that those who are unemployed were more likely to smoke(Montgomery *et al.*, 1998, De Vogli and Santinello, 2005), proportion of smokers were higher among unemployed, early retirement and unskilled worker(Osler, 1992).Higher job status such as professional, managerial and technical was associated with higher sustain rate compared to blue collar job(Sorensen *et al.*, 1986). However, it is not known whether occupational status influence smoking cessation outcome.

1.4.2 Psychosocial Factors

a. Social support

Social support such as advice and encourage to stop smoking and stop smoking together should be a positive factor to stop smoking. It was suggested that people with poor social support, low self esteem or mastery are more susceptible to involve with substance abuse(Koval and Pederson, 1999).

b. Surrounding People Smoking

The presence of other smokers in the household was a negative predictor for smoking cessation(Yang *et al.*, 2006, Zhou *et al.*, 2009, Garvey *et al.*, 1992, Matheny and Weatherman, 1998, Gourlay *et al.*, 1994, Herd *et al.*, 2009, McDermott *et al.*, 2009).

A prospective cohort study by Manchon Walsh et al from 1995 – 2003 showed significant difference were found in the abstinence rates at 12 months by smoker partner status. Forty six point five percent of patient without smoking partner managed to achieve abstinence compared to patient with smoking partner (28.3%). Having a smoker partner significantly determine relapse one year after beginning of the cessation program(Manchon Walsh *et al.*, 2007). Presence of other smoker also found to be a predictor factor to smoking relapse in ATTEMPT study(Zhou *et al.*, 2009).

c. Stressful Life Event

Some people are unable to cope well with stress and smoking has been identified as one of the coping mechanism(McKee *et al.*, 2003). A few studies have shown that stressful life event was significantly associated with fail to stop smoking or relapse(McKee *et al.*, 2003, Weaver *et al.*, 2000, Hymowitz *et al.*, 1991).

1.4.3 Addiction

a. Level of Addiction

The ATTEMPT cohort study found that smoking relapse was associated with higher nicotine dependence(Zhou *et al.*, 2009). Many other studies also have shown similar findings(Ferguson *et al.*, 2003, Rohren *et al.*, 1994, Richmond *et al.*, 1993). However, the local study by Wee et al (2010) found that Fagerstrom Test of Nicotine Dependence was not a predictor factor to success to stop smoking(Wee *et al.*, 2010).

b. Other substance abuse, caffeine intake

Difficulty to stop smoking is due to addiction. In relation to this, Krall et al estimated the rates and predictors of late smoking relapse in 483 men in a prospective study for up to 35 years. In multivariate regression models, coffee and alcohol consumption and user of cigars or pipes significantly increase the risk of smoking relapse(Krall *et al.*, 2002). However, this study was done among former smoker who relapsed after 2 years of abstinence. A study among women in Australia found that illicit drug use was significantly associated with smoking relapse(McDermott *et al.*, 2009). Westmaas et al (2005) reported that among men, caffeine and alcohol consumption are significant predictors to smoking during first day of quitting attempt(Westmaas and Langsam, 2005).

d. Withdrawal Symptoms

There were few studies that showed smoking relapse was associated with the presence of withdrawal symptoms(Zhou *et al.*, 2009, John *et al.*, 2004, Herd *et al.*, 2009). However, another study found that high score of withdrawal symptoms did not predict relpase(Norregaard *et al.*, 1993).

1.4.4 Past smoking history

a. Age of smoking initiation

Age of smoking initiation significantly related to smoking cessation. Numerous studies have shown that majority of smokers started to smoke during teenage(Rapeah *et al.*, 2008, Hammond, 2008, McNeill *et al.*, 1988). For instance, younger age of smoking initiation is associated with continuation of smoking or more likely to fail in smoking attempt(Khuder *et al.*, 1999, Paavola *et al.*, 2004, Paavola *et al.*, 1996).

b. Smoking Duration

McDermott et al(2009) reported that daily smoker for more than 6 months was associated with smoking relapse(McDermott *et al.*, 2009). Other study By Matheny et al (1998) found that those who smoked longer duration was also associated with smoking relapse (Matheny and Weatherman, 1998).

1.4.5 Past history of quitting attempt

The most critical period for smokers to relapse is during the first week after they attempted to stop. Garvey AJ in 1992 found that relapse rates were much higher during the early days and weeks following quitting attempt. Shorter periods of abstinence on prior quit attempts, larger pre-cessation consumption of alcoholic beverages, and poor pre-cessation levels of confidence after cessation pertaining to their ability to continue abstinence were more likely to relapse there after(Garvey *et al.*, 1992). Smokers who have failed quitting attempt recently are more likely to try again but also more likely to relapse than those who have not tried .

1.4.6 Motivation

Motivation has been always being thought as an important factor to prevent relapse. Self efficacy which is defined as 'individual's belief that he or she can successfully execute the behaviours that a situation requires to produce the outcome that is desire'; is a predicting factor to prevent relapse(Condiotte and Lichtenstein, 1981, Herd *et al.*, 2009, Ferguson *et al.*, 2003). The stages of readiness of smokers such as pre contemplation, contemplation, action and maintenance play an important role to determine the success. Those with action stage were more successful than those with contemplation stage (Rohren *et al.*, 1994, Miguel Barrueco Ferrero, 2007). However,

in ATTEMPT study motivation predicts future attempts but not of relapse following attempts(Zhou *et al.*, 2009).

1.4.7 Weight Concern and Weight Gain

Having weight concerns appears to lower smoking abstinence rate in smokers who are trying to stop(Clark *et al.*, 2006). In examining the impact of weight concerns on the 12 week point-prevalence smoking abstinence by Clark MM et al, 26% of non-weight-concerned smokers quit smoking compared to 22% of weight-concerned smokers ($p=0.06$). Motivation to quit smoking was found to be significantly lower in those with weight concern ($P<0.001$)(Clark *et al.*, 2004). On the other hand, smokers who reported having elevated post-cessation weight gain or smokers who reported that they will return to smoking if they gain weight after stopping smoking, frequently demonstrated poor smoking abstinence rates(King *et al.*, 2000).

1.4.8 History of chronic disease

Smokers may stop smoking after being diagnosed as hypertension or heart disease. However, a systematic reviews of the Cochrane Tobacco Addiction Review which was done to determine the success of smoking cessation interventions in cardiovascular disease patients(Wiggers *et al.*, 2003) did not prove this. Twelve studies have been reviewed showing very limited effects and the reasons for lack of success were not clear. ATTEMPT study reported that concern about chronic health condition was not associated with smoking cessation outcome(Zhou *et al.*, 2009). Therefore, it is unknown whether being healthy or no chronic disease is associated with fail to stop smoking.

1.5 Rationale of the study

To provide data on failure rate among smokers who attempted to quit smoking. Previous local studies (NHMS, 2006, Manimaran, 2003) has shown high prevalence of smokers and number of quitting attempt . However, we don't have many local data on associated factors of success or failure to stop smoking. There are numerous data mainly from the western countries which may not be generalized to our population due to different nation, culture and life style.

The fact is that we have many quit smoking clinic services provided by Klinik Kesihatan . However, this service may be underutilised. From this study we can know the awareness among smokers regarding the availability of this service. This data can be combined with QSC attendees. More campaign and promotion up to the national level can be done to encourage smokers to attend quit smoking clinic.

This study can provide the characteristics of smokers who attempted to quit and its associated factors risk to fail. By knowing the associated risk factors, we can identify those who are vulnerable to fail. This knowledge can be implemented for our QSC clients to reduce failure or relapse rate.

CHAPTER TWO

OBJECTIVES

2.1 GENERAL OBJECTIVES

To determine the prevalence and its associated factors of relapse among ever smokers who attempted to stop smoking attending Klinik Rawatan Keluarga, HUSM.

2.2 SPECIFIC OBJECTIVES

1. To determine the prevalence of relapsed among ever smokers who attempted to stop smoking.

2. To identify the associated factors of relapsed among ever smokers who failed to stop smoking.

2.3 HYPOTHESIS

Factors like current age, educational level, income, employment status, marital status, started at young age, chronic disease, duration of smoking, level of addiction, number of quitting attempt, motivation, social support, surrounding people who smoke, stressful life event, weight concern, withdrawal symptoms and caffeine intake are associated with relapsed among smokers who attempted to quit smoking.

CHAPTER THREE

METHODOLOGY

3.1 STUDY DESIGN

A cross sectional study.

3.2. POPULATION AND SAMPLE

3.2.1 SOURCE POPULATION

Patients attending Klinik Rawatan Keluarga, Hospital Universiti Sains Malaysia (HUSM), Kubang Kerian, Kelantan. HUSM is one of the teaching hospitals in Malaysia. It is situated 3 km away from Kota Bharu, the capital city of Kelantan. Klinik Rawatan Keluarga which is under the Family Medicine Department, is an outpatient clinics that provides primary care level services for the population in Kota Bharu.

3.2.2 STUDY POPULATION

Based on inclusion and exclusion criteria below:

3.2.3 INCLUSION CRITERIA

- Male and female
- Age 18 years and above
- Current smokers
- Ex-smoker

3.2.4 EXCLUSION CRITERIA

- Smoker who is not smoking for more than 1 month but less than 6 months
- No history of quitting attempt

- Acute psychiatric disorder
- Poor memory
- Mental Retardation
- Substance abuse

3.2.5 SAMPLE SIZE CALCULATION

For objective 1, the sample size to calculate the proportion of smokers who attempted to stop smoking was done using single proportion formula.

$$\mathbf{N} = \left[\frac{\mathbf{Z\alpha/2}}{\Delta} \right]^2 P(1-P)$$

Δ

P = Proportion who relapsed based on pilot study

= 0.77

N = Minimum required sample size

Z = Value of standard normal distribution = 1.96

Δ = Precision = 0.05

$$= \left[\frac{1.96}{0.05} \right]^2 0.77(1-0.77)$$

$$= 1536 \times 0.706(0.225) = 268$$

Sample size calculation to determine the prevalence of attempted to quit smoking among current smoker in KRK was done using single proportion formula based on the previous pilot study. The minimum required sample size is 268. However after considering the non-response rate of 10%, the sample size is 294.

For objective 2, the sample size calculation for each associated risk was also based on the pilot study using power and sample size software (version 3.0) for comparing two

proportion was done for categorical variables (refer Appendix 3) and comparing two means was done for numerical variables (refer Appendix 4). The biggest sample size obtained for this objective was weight concern (total n = 277). Therefore, the sample size for objective 1 was taken since it gave the biggest sample size.

3.2.6 SAMPLING METHOD

The sampling frame was ever smokers with history of quitting attempt. Smokers were identified among outpatients who registered at Klinik Rawatan Keluarga by systematic sampling in the ratio of 1:2.

Every 1 in 2 smokers who fulfil the inclusion and exclusion criteria was invited to participate in the research project. Ever smokers with history of quitting attempt is identified with questions in Appendix 1.

3.3 RESEARCH TOOLS

3.3.1 QUESTIONNAIRES

Questionnaires consisting of

1. Socio demographic, smoking history and social history characteristics.

2. Addiction level is one of the associated factors examined in this study. The Malay version of Fagersrom Test for Nicotine Dependence (FTND-M) is a set of

questionnaires which has been widely used at health clinics to assess the addiction level. The original FTND is in English version was developed in 1978 known as Fagerstrom Tolerence Questionnaire provides a short and convenient self report on addiction level(Todd F Heatherton *et al.,* 1991). The current version of FTND (revised in 1991) contains 6 items which are derived from 8 items questionnaire (FTQ 1989)(Todd F Heatherton *et al.,* 1991) .The 6 items are -time of the first cigarette after waking, the difficulty to avoid smoking at the smoking forbidden places, the most difficult cigarette to give up in a day, the amount of the cigarettes used a day, the frequency of smoking during the first hours after awakening compare to the rest of the day and smoking even though they are so ill. FTND scores ranges from 0 to 10 which can be interpreted as: 0-3 (low addiction), 4-5 (moderate addiction) and 6 -10 (high addiction).

In Malaysia, FTND was translated and validated by Anne et al (2011) with good validity and reliability. The optimal cut off point for FTND-M was more than 2 with the sensitivity of 70.1%, specificity of 70%, positive predictive value (PPV) of 79.7% and negative predictive value (NPV) of 58.3%. The study had similar internal consistency with the original version of FTND with Cronbach's alpha of 0.6 .Test-retest reliability was fair.

3.3.2 PILOT STUDY

A pilot study was done on 8 – 19 Mac 2010 at Klinik Kesihatan Gunong, Kelantan to determine the sample size and to estimate the length of time required to complete the questionnaire. A total of 40 respondents were included in the study. The mean age of the respondents was 44 years old. From the study, all of them were Malay and there was

only one female. Klinik Kesihatan Gunong is a health clinic, one of the primary care clinic under the Ministry of Health, Malaysia.

3.4 DATA COLLECTION PROCEDURE

The study was conducted from July 2010 until September 2010. All subjects who agreed to participate in the study were given guided self administered questionnaires after taking the informed consent. The complete questionnaires were collected and checked by the researcher on the same day.

3.5 DATA ENTRY AND ANALYSIS

All data were analysed using the Statistical Package for the Social Sciences (SPSS) program for windows (version 17.0). Data cleaning and exploration were done.

Descriptive analysis was done for Objective One.

Objective 2 was to determine the associated factors to relapsed among ever smoker with history to stop smoking attending KRK, HUSM. The dependent variable was current smoker who relapsed. The independent variables were current age, educational level, income, employment status, marital status, started at young age, chronic disease, duration of smoking, level of addiction, number of quitting attempt, motivation, social support, surrounding people who smoke, stressful life event, weight concern, withdrawal symptoms and caffeine intake. The analysis for this objective included:

1. Simple Logistic Regression analysis was done to determine the potential associated for relapsed among ever smokers with history of quitting attempt

2. Multiple Logistic Regression was used to look for associated factors for relapsed among ever smokers with history of quitting attempt while controlling for other confounders in the model.

Simple Logistic Regression (SLR) was used as a screening in selection of variables for further analysis, the variables with P value less than 0.3 and clinically significant variables were selected into Multiple Logistic Regression. P value in SLR was set larger than the level of significant to allow for more important variables to be included in the model. The methods that were used for variables selection were backward and forward logistic regression to obtain final models. Results presented by 95% confidence interval and adjusted odds ratio. The level of significant analysis was set at $p < 0.05$.

Fitness of the model was tested with Hosmer and Lemeshow goodness of fit test. The model was perfect fit if the P value approached to one. The classification table and receiver operating characteristics (ROC) curve were also used to determine the fitness of model. The high overall percentage in the classification table and area under the curve toward one in the ROC curve showed that the model was fit. This also determines the specificity and sensitivity of the model.

3.6 DEFINITIONS OF OPERATIONAL TERMS

Smoker

Someone who smokes any tobacco product regularly

Current smoker

Respondent who reported to be a regular smoker and still smoking within 1 month, at

the time of the survey

Ex smoker

Respondent who was a smoker and reported has stopped smoking for at least 6 months.

Ever Smoker

Current smoker and ex smoker

Quit attempt

a) Planned

- Self planned - seriously thought to stop smoking and set a quit date.
- Attended stop smoking session/clinic – attended or referred to stop smoking clinic which is done at any Klinik Kesihatan or support group

b) Unplanned – sudden decision not to smoke anymore including those that might be remaining in the current pack.

Managed to abstinence for at least one day.

Addiction level

Addiction to smoking based on Nicotine Dependence: Fagerstrom Test for Nicotine Dependence (FTND)

Marital Status

Married – currently married

Not married – single or divorced/widow

Educational Level

A formal education acquired by respondent.

Low - not schooling or attended formal school until form 3

Middle - form 4 until Diploma

High - at least first degree

Motivation

Low motivation is defined as pre-contemplation and contemplation phase. High motivation is defined as preparation and action phase.

Social Support

Presence of physical or emotional comfort given by the surrounding people such as family members, friends or colleagues to encourage smokers to stop smoking

Stressful life event

Event or experience that produces severe strain:

a) interpersonal loss events (death of close friends or relative, divorce)

b) personal financial problem

c) move to a new residence

d) life threatening illness or injury

Withdrawal Symptoms

Abnormal physical or psychological features that follow the abrupt discontinuation of smoking

Caffeine Intake

Taking any drink or food which contains at least 70mg caffeine per day. For coffee, at least 1 cup per day and for tea, at least 2 cups per day.

3.7 Approved by Research and Ethics Committee

The protocol for this study was approved by the Research and Ethical Committee, School of Medical Sciences, Universiti Sains Malaysia on 30th June 2009.

Cross Sectional Study

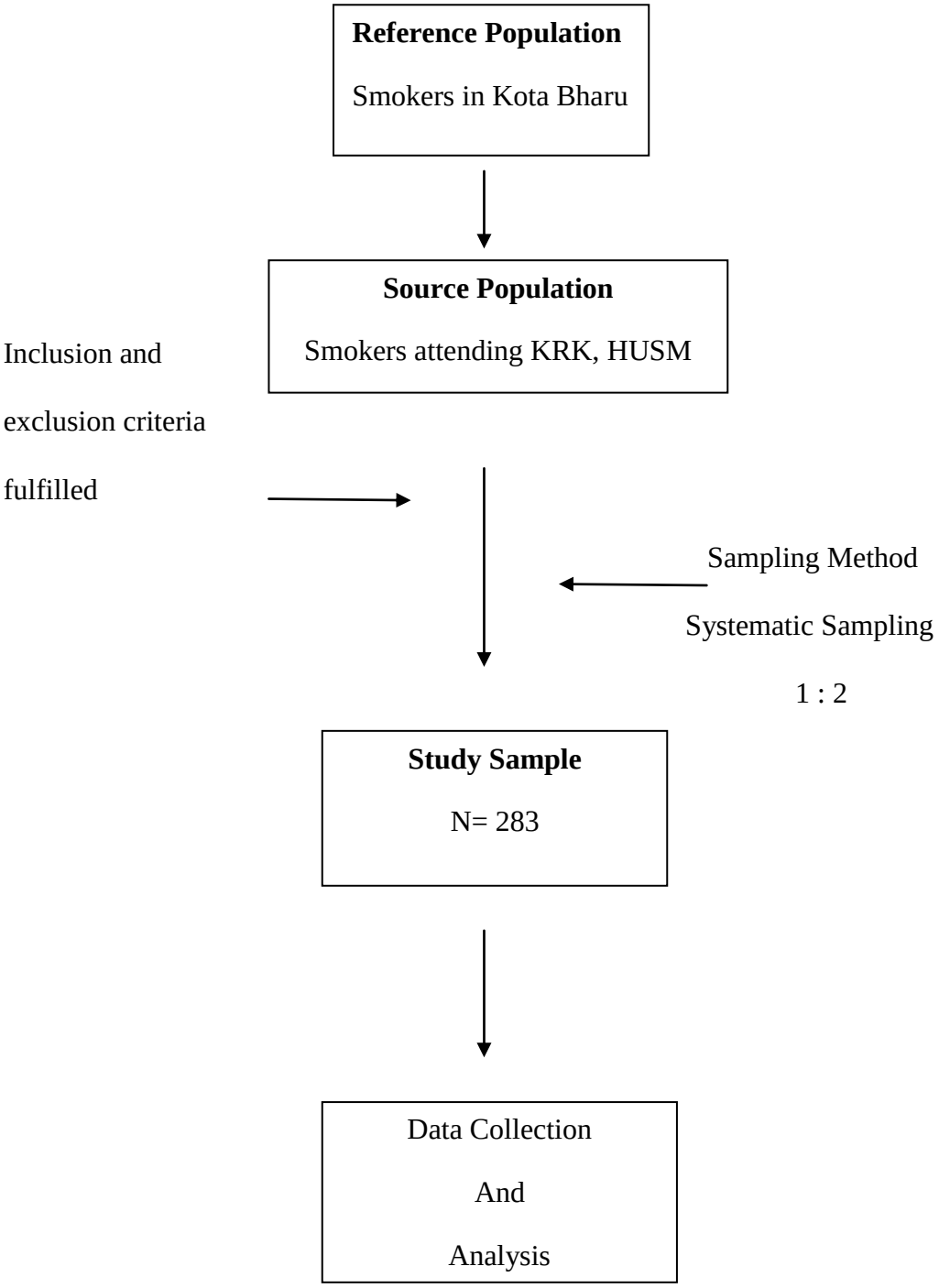

Figure 3.1 Flow chart of the study