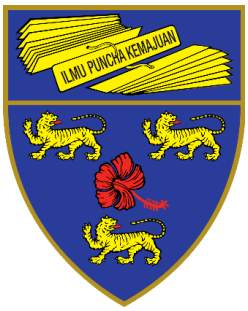

PROPOSAL PAPER

CROSS-CULTURAL ADAPTATION OF A BETEL QUID CESSATION PROGRAM AND EVALUATION OF ITS EFFECTIVENESS IN A MALAYSIAN HIGH-RISK COMMUNITY

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EXECUTIVE SUMMARY

Betel quid chewing is known as one of the most common cause of oral cancers (OC) in Malaysia (OHD, 2018) and more than 50% of OC patients present at the later stage of the disease. Chewing betel quid too can result in submucous fibrosis, malnutrition, gastric ulcer, hypertension, coronary artery spasm, and placental damage. In 2010, the World Health Organisation recognised chewing betel quid as a habit that binds the chewers with a dependency syndrome. Hence, a spontaneous withdrawal or cessation of the habit might not be possible nor achievable by just a few brief advises. Thus, a cessation program is highly necessary. Till to date, there is no cessation program developed targeting specially the betel quid chewers in Malaysia. Thus, it is timely for Malaysia to adapt a cessation program for its high-risk groups to educate and practically guide them to cease the habit and lead a healthier lifestyle.

(150 word count)

1.0 INTRODUCTION

1.1 Betel Quid & Its Composition

Betel quid (BQ) is one of the most common risk factors for oral cancer in Malaysia after cigarette smoking and alcohol consumption (Ghani et al., 2011). BQ is a collective term used to describe the diverse composition of its ingredients. International Agency For Research On Cancer (IARC) under World Health Organization (WHO) in 2004 stated the term '**quid**' can be defined as 'a substance, or mixture of substances, placed within the mouth and usually contains at least one of the two basic ingredients; which is either tobacco or an areca nut. According to Winstock (2002), the BQ composition varies according to the regions of the world, country, ethnicity, and personal preference of its users.

BQ mainly includes areca nut (AN), betel leaf and slaked lime (Paulino et al., 2011). It is usually prepared by smearing the betel leaf with slaked lime and then an AN is added to the preparation. It may also contain tobacco and other ingredients such as spices; cardamom, saffron, cloves, aniseed, turmeric, mustard or sweeteners or flavouring agents. These extra ingredients are added based on user's preferences and locality's inclinations. Nevertheless, the primary ingredient of a BQ is the AN (IARC, 2004).

AN is the seed of the palmaceous Areca Catechu tree. The size of the nut is approximately like an egg and is in orange-yellowish colour once it's riped and in green colour when it is unripe. The nut is ussually separated from the fruit and is incorporated into BQ after drying or processing it. And some do consume it fresh. IARC (2004) cautioned to not refer AN as betel nut as it is botanically incorrect.

Betel leaf is scientifically termed as 'Piper Betel Linn'; which is a leaf from a vine tree. They normally grow in hot and humid climates and are used to wrap the BQ preparation. **Slaked lime** is derived from coral, sea shells (shell lime) or quarried limestone and then are mixed with water. In some countries, there are also red variation of slaked lime (IARC,2004).

Figure 1.1 Areca Nut

Figure 1.2 Betel Leaf

Figure 1.3 Preparation of a Betel Quid

1.2 Carcinogenecity of Areca Nut

Due to overwhelming evidence, WHO classified BQ and AN as **Group 1 carcinogens**. This category is used when there is a sufficient evidence of a particular agent's carcinogenic activity in humans. Usually an epidemiological or animal experimental studies are used to evaluate the strong evidence of an agent's exposure in developing cancers in humans (IARC, 2004).

As early as 1996, Lu CT et al. stated **BQ chewing was positively associated with the risk of oral cancer** with an adjusted odds ratio (AOR) of 58.4 in a case control study among Taiwanese in Changhua County. A **dose-response relationship** was able to be demonstrated by authors on AN's exposure in developing oral cancer. The dose-response relationship is crucial concept in the scientific field of toxicology because it enables the researchers and

clinicians to determine the harmful effects of a substance to human bodies (Wexler, P., & Abdollahi, M., 2014). **Odd ratios** (OR) is a means to measure the association between an exposure and an outcome. The OR represent the likelihood (or odds) of an outcome to occur in the presence of an exposure compared to the odds of the outcome in the absence of the exposure (Szumilas M., 2010).

In Lu CT et al. (1996) study, the frequency of BQ's daily use and the number of years BQ chewing was practiced had an impact on oral cancer occurence. The **risk of oral cancer was seen higher with the greater number of BQ chewing years**; AOR of 93.7 for those chewed for 21 to 40 years and AOR of 397.5 for those who chewed for more than 40 years. In the aspect of **quantity of BQ pieces chewed daily** (pcs/day), the AOR was 26.3 (for those chewing <10 pcs/day), 51.2 (for those chewing 10-20pcs/day) and 275.6 for those chewing (>20 quids/day). Wong TY et al. (1992) quoted that in an animal study where BQ was placed within a hamster's cheek pouch, the **quid was an oral carcinogenesis-promoting factor** and not just an initiator.

Jeng et al. (1994) reported the aqueous **extracts of AN** and unripe Piper betel fruit **induced DNA strand breakage** and **decreased cell survival and proliferation** in a dose-dependent manner in a cell proliferation assay experiments. Kuo et al. (1994) reported in his study that **mutations of Ki-ras oncogene** codon 12 was found in Oral Squamous Cell Carcinoma (OSCC) patients who chewed BQ in Taiwan. They indicated that Ki-ras oncogene activation **played a vital role in the development of oral cancer in BQ chewers**.

Shirzaiy M et al. (2020) indicated that long term use of AN can lead to OSCC. But prior to that, AN chewing will lead to formation of **Oral Submucosal Fibrosis (OSF).** OSF is a

precancerous condition with the highest malignant potential among other oral mucosal lesions. AN causes overproduction of collagen by stimulating the fibroblasts. The overproduced collagen will be deposited in the soft tissue thus decreasing the oral mucosa's flexibility. Clinically, OSF is commonly manifested as a severe reduction in the mouth opening due to rigidity and blanching of oral soft tissues which gives rise to difficulty in speech, chewing, and swallowing. And this condition is irreversible.

1.3 Other Effects of Areca Nut

Arecoline is the primary alkaloid found in AN and has a numerous effect on the systemic body besides the mouth (Javed F et al., 2010). Arecoline has the **potency to traverse the placental and the blood–brain barrier** besides the oral mucosal tissue. Arecoline is a partial muscarinic agonist that crosses the blood–brain barrier and bind to the gamma aminobutyric acid (GABA) receptors which leads to production of a range of parasympathetic effects such as **accelerated heart rate and increased blood flow** in both the external and common carotid arteries (Asthana et al., 2006). It also has cholinergic effects of **decreasing diastolic blood pressure** (Lin SK et al. 2002). As arecholine can tranverse the placenta barrier; it also is associated with **neonatal withdrawal syndrome and placental damage** (Lo´pez-Vilchez MA et al., 2006).

Giri S et al. (2006) claimed the habitual users of BQ are associated with **dependency syndrome** (DS). Arecoline is recognized as the **4th most consumed psychoactive substance** in the world; after nicotine, ethanol and caffeine (Giri et al. 2006; Chou et al. 2008; Volgin et al. 2019). Patient with DS usually experiences **increased concentration, mild euphoria, warmth, a sense of well being, relaxation, postprandial satisfaction and a withdrawal**

syndrome associated with insomnia, mood swings, irritability and anxiety, the severity of which can be compared with that of amphetamine use. It also **increases the alertness** of the users, have **anti-migraine properties** and **enhanced capability to work**. In Taiwan, AN serve as an **energizing stimulant** for young industrial workers who needed to endure long hours of repetitive work. Besises that, the betel stalls also **provided a social gathering ground and a sense of community** for the industrial workers that had just migrated to the city (Tham J et al., 2017).

In terms of **metabolism**, studies claimed AN appears to regulate metabolic signals for human appetite for food in both fed and fasted states and was **linked with obesity and the metabolic syndrome** (Lin SK et al. 2002). Boucher et al. (2002) stated arecoline is associated with central obesity and type II diabetes. Boucher et al. (1994) in his earlier study showed that exposure to AN were related to an **increased risk of hyperglycaemia occurrence**. Park YB et al., (2002) demonstrated that arecoline inhibits the intestinal acetyl co-enzyme acyltransferase (ACAT) and pancreatic cholesterol esterase (pACE) leading to 25% decrease in cholesterol absorption in an animal study.

Strickland S et al. (2003) claimed participants in his study mentioned chewing AN **helped them to control hunger** which also can be **associated with malnutrition** among BQ chewers. In the aspects of nutrition, Ogunkolade WB et al. (2006) too noted that AN chewers have **high prevalence of vitamin-D and iron deficiency** which aggravates their systemic conditions. AN aggravates effects of Vitamin D deficiency due to its powerful effect of increased 25(OH)ase expression, leading to a decreased in serum calcitriol levels.

Deng et al. (2001) in their study stated patients who consumed up to six nuts were presented with some gastric disorders. Hung CR (2005) in an animal study showed an **exacerbation of gastric ulcers** were observed in the AN-fed rats compared to the control group. In another study by Tsai et al. (2003), they reported that consumption of more than 200 quids can increase a person's **risk for hepatocellular cancer**. Javed F. et al. (2010) stated that chewing BQ can significantly insult periodontium and was associated with **periodontal inflammation**. Periodontal inflammation on the other hand is a contributing factor for the initiation and progression of certain systemic conditions in AN chewers.

BQ chewing is also **connected with the occurrence of coronary artery spasms** due to the parasympathomimetic effects of arecoline on blood vessels with abnormal endothelium. AN give rise to a high concentration of arecoline in the circulation of patients with coronary artery disease. This arecholine obstructs the effect on the high-density lipoprotein receptor and impede the uptake of low-density lipoprotein by the liver thus resulting to **enhanced atherogenesis and escalates the vascular damage** (Hung DZ et al., 1998).

In **endocrine system**, arecholine can cause an increased in T3, T4 release and suppression of thyroid stimulating hormone (TSH). Arecoline too decreases melatonin concentration in plasma but increases the serotonin levels. In the hematologic perspective, Peng K et al. (2010) cautioned medical practitioners to **use blood donated by a BQ chewer for blood transfusion** as they claimed blood contaminated by AN are poor in quality and maybe cytotoxic to receiver's red blood cells (RBCs). They observed drastic morphological changes in AN-extract-treated RBC in the study. Apart from that, a continuous exposure of AN alkaloid **destroys important genes such as p53** which leads to **proliferation of cells with damaged DNA and ultimately a neoplastic change** (Chatterjee A et al., 1998).

In the aspect of **respiratory system**, arecoline has also shown to constrict bronchial smooth muscles thereby **causing difficulties in respiration**, especially in patients with respiratory tract disorders (Taylor RF et al., 1992). They observed 20% decrease in the forced expiratory volume in 1 second (FEV1) and also a 30% fall in FEV1 by 150 min after chewing. The reproducible effect proved that arecoline was the contributing factor. In adition, in United Kingdom, the **rate of hospital admission for acute asthma cases was seen higher** among Asians who chewed AN compared to others. Thus, AN was found to be a factor that affects the control of asthma and the severity of asthma attacks.

Finally in the aspect of **fetus**, pregnant mothers who consumed AN have **higher incidences of low birth weight, low birth length and preterm births** (Senn M et al, 2009). Birth weight was regarded as 'low' if <3,000 g (Barker, 1995) while the birth length was considered as 'short' if <48 cm (NIHRD, 2013). As BQ chewers have a **higher concentration of heavy metals in their blood**; the substance such as lead, arsenic and cadmium can pass the placental barrier and harm the fetus (Al-Rmalli SW et al., 2011). Apart from that, a study claimed pregnant women who chewed BQ have incidences such as **spontaneous abortion and still births** (M. J. Yang et al. , 2001).

In 2014, Garg A et al. concluded that AN is a harmful food product due to its adverse effects. He asserted that there is an **urgent need for policy makers to prohibit the use BQ products** and regulate the production of machined BQ. Shah et al., 2002 and Oakley et al., 2005 too claimed BQ chewing practices should now be recognised as an **important public health issue** as this ill habit possess a vast deleterious health effects to its users.

Table 1.1 Summary of Adverse Effects of Betel Quid Chewing Habit

Adverse Effects of Betel Quid Chewing
Mouth • Oral Cancer • Submucosal Fibrosis • Periodontal inflammation **Metabolism** • Obesity • Metabolic syndrome • Hyperglycaemia **Nutrition** • Vitamin-D and iron deficiency • Malnutrition **Gastrointestinal system** • Gastric ulcers **Liver** • Hepatocellular cancer **Cardiovascular system** • Hypertension • Coronary artery spasms **Endocine system** • Increase in T3 and T4 release • Suppression of thyroid stimulating hormone (TSH) **Hematology** • Poor quality of blood – contradicted for blood transfusion **Respiratory system** • Difficulties in breathing • Risk of hospitalisation for acute asthma **Preganacy & Fetus** • Neonatal withdrawal syndrome • Placental damage • Higher incidences of low birth weight • Low birth length • Preterm births • Spontaneous abortion • Still births

1.4 Problem Statement

The central problem to be researched for this proposed study is the lack of any development or adaptation of a cessation programme for BQ chewers in the country although there is an adequate understanding on the seriousness of this risk habit and the evidence of high prevalence among the high risk groups in Malaysia.

First, the issue of **high prevalence of BQ chewing habits among the high risk groups**. The global prevalence was found to be 10-20% in 2002 by Gupta & Warnakulasuriya. The authors in their papers quoted that even in 1996 that 22% of men and 47% of women interviewed in rural Sawarak used AN daily (Strickland & Duffield). And another paper by Zain et al. reported that 22.5% (37 of 164) of indigenous people in Sarawak were current BQ chewers and 62% (91 of 147) Indians in Malaysian estates were habitual BQ chewers in 1999. A decade later, Ghani et al. (2011) conducted a nationwide survey on oral mucosal lesions among 11,697 adults in all fourteen states in Malaysia and reported 7% of Malaysian adults were found to be current BQ chewers. And the study further mentioned that the females in the high risk categories surpassed the global prevalence of BQ chewing with the Malaysian Indian females having the prevalence of 28.9% and followed closely by the females in Sabah & Sarawak Indigenous community with the prevalence of 28.4%. The study too found that females were less likely to cease BQ habits in their lifetime compared to males; who showed a sharp decline in ceasing this habit after 15-25 years of chewing. Thus, there is a dire need to intervene this high prevalence of ill habits among the high risk groups in Malaysia.

The second issue for this scenario is the **lack of recognisation that BQ chewing habit is an addiction**. Bhat SJ et al. (2010) were one of the few first authors that published regarding

the dependency syndrome of chewing BQ with areca nut only and without the inclusion of tobacco. For the past 50 years, most attention was given to cigarette smoking as it was widely recognised as an addiction while areca nut's dependency syndrome was not explored well. Only in 2010, WHO recognised BQ chewers to be experiencing a dependency syndrome. **Dependency syndrome** is defined as a syndrome in which the user experiences a strong desire to engage in a negative behaviour, having difficulty in controlling the behaviour and thus continue to practice the behaviour despite being aware of its harmful consequence. Bhat SJ (2010) reported even though the levels of dependence symptoms were low (13.6%) among the participants of his study, 44% of chewers claimed they were having difficulty in ceasing the habit. They were having at least one of the following symptoms: continued use despite illness or mouth wounds, difficulty refraining from chewing in forbidden places, or cravings during periods of abstinence. Little MA & Papke RL (2015) quoted that BQ chewing habit is an orphaned addiction since the habit was endemic to South Asian and Pacific population, thus the Westerners are displaying an indifferent attitude to it. They further claimed the head of World Health Organization (WHO)'s substance abuse unit; Vladimir Poznyak stated that WHO "have no plans or activities to promote in this field" at present. Even in Malaysia, we observe a similar indifferent attitude with lack of initiative seen to intercept this behaviour at the high risk groups in the country.

The third issue is **lack of efforts to develop a cessation program for BQ chewers**. Since there is a mounting evidence that BQ chewing habit can increase the risk of multiple diseases especially cancers (Song H et al., 2015), heighten efforts should be placed to either develop or adapt a cessation program for BQ chewers. Since AN users who tried to quit the habits were undergoing withdrawal symptoms that are similar to nicotine withdrawal sypmtoms pattern (Winstock AR, 2000), a **smoking cessation based behavioural**

intervention can be used by targetting the adverse effects of AN and as well to promote cessation (Little MA & Papke RL, 2015). They too proposed since **cognitive-behavioral therapy** is widely used to assist people to stop smoking, a similar behavioural therapy will be helpful and would possess as a good starting point for the development of AN cessation interventions. Since Moss J. et al. (2015) developed a BQ cognitive behavioural cessation program specially for BQ chewers in the islands of Guam and the intervention has **yeilded a high self-reported cessation rate (65%)**, efforts can be directed to adapt the program to the Malaysian high risk communities. After a period of adaptation, this program can be extended to medical counterparts for training and implementation accordingly in their related fields. Since the original study mainly conducted the **intervention as group-based**, it is very advantageous to Malaysian high risk communities as the BQ chewing habits here are culturally-linked and community-based. Apart from that, Shirzaiy M et al. (2020) too emphasized the **most important treatment modality for BQ chewers with oral submucosal fibrosis is cessation and education programs**. He further claimed without habit cessation, the OSF condition has a high possibility for a malignant transformation. Maling TH et al. in 2016 conducted a quasi-experimental study using a structured Oral Health Educational module based on Health Belief theory to intervene a high risk community in Limbang, Sarawak. After the structured educational program, there was a significant drop in the number of current BQ chewers (17.6% at 1-month and 23.5% at 3-month post intervention). In the aspect of frequency of BQ chewing, there was a drastic drop in the daily chewing section (66.7% at 1-month and 88.9% at 3-month post intervention). In the aspect of commitment to quit habit, more than half stated will reduce or modify their habit after attending the educational program (66.7% at 1-month and 58.3% at 3-month post intervention). Thus, this further proves that a structured educational program is very crucial in tackling conditions with high risk behaviours that involves closely with addiction or dependency syndrome.

1.5 Research Questions

A. What are the demographics, BQ chewing behaviours, BQ composition and BQ dependency levels among its users in a high risk community in Malaysia?
B. What are the reasons for BQ chewing, the readiness and self perceived barriers to cease BQ habit among users in a high risk community in Malaysia?
C. Can a BQ cessation program be adapted to a high risk community in Malaysia?
D. What is the effectiveness of a BQ cessation program in a high risk community in Malaysia?

1.6 Aim and Objectives

1.6.1 Aim of the study

The aim of this study is to cross culturally adapt a BQ cessation program for a Malaysian high-risk community and evaluate the effectiveness of the adapted BQ cessation program using a combination of self- reported cessation rates and salivary biomarkers measurements.

1.6.2 Objectives of the study

i. To determine the demographics of BQ chewers, BQ chewing behaviours, BQ composition and BQ dependency levels among its users in a high risk community in Malaysia
ii. To determine the reasons for BQ chewing, the readiness and self perceived barriers to cease BQ habit among users in a high risk community in Malaysia
iii. To adapt a BQ cessation program for a Malaysian high risk community
iv. To evaluate the effectiveness of the adapted BQ cessation program through :

a) self-reported cessation rates

b) salivary biomarkers measurements

1.7 Hypothesis

Objective 4

i. **Null hypothesis** : There is no significant difference in cessation rate among the intervention group compared to the control group at 3 months follow up assessment

ii. **Alternative hypothesis** : Intervention group will produce a significantly greater cessation rate compared to the control group at the 3-months follow-up assessment

1.8 Rationale of the Study

Firstly, since there is an **established BQ cessation program** with at least 5 years of implementation (Moss J et al., 2015), Malaysia can tap into the essentials of this program for the BQ users in this country. As the structure of the cessation program was modeled after a group-based smoking cessation program, this structure resembles the '***Kesihatan Oral Tanpa Amalan Rokok'*** (KOTAK) program that is currently being held nationwide by the government dentist. Due to the **familiarity of the intervention structure**, this intervention can be easily utilised by the Malaysian dentist as all dentists were adequately trained under the KOTAK cigarette-smoking cessation program.

Secondly, the concept and framework of **Cognitive Behavioral Therapy (CBT) has yielded a high success rate**. Raja M. (2014) claimed a CBT based group cessation yielded more success rate compared to control group which only educated BQ chewers with a Basic Health Education model. Moss J et al. (2015) who utilised a CBT program too reported the study yielded a surprising 65% of self reported cessation rate among the study participants. The

cognitive component of the program that addresses the chewer's attitude and beliefs and the **behavioural component** that aims to replace chewing-promoting behaviours with behaviours conducive for quitting **is a very advantageous and comprehensive intervention**.

Thirdly, this **model of the therapy is flexible** as it can accomodate a **social component** to **increase the sustainability of cessation program in a community** by educating and empowering the participant's community (eg. the villagers of chewers). Another benefit from the CBT program is that the participants possessed a higher degree of motivation to quit and experienced lower withdrawal symptoms post quitting (Schnoll RA, 2005). A study stated that **without any interventional program, BQ chewers face difficulty in quitting** their ill behaviour due to the dependency syndrome.

Fourthly, with the **advent of liquid chromatography-mass spectrometry (LC-MS)** technology, the appearance and disappearance of betel alkaloids (biomarkers) can be measured. Thus, the **effectiveness of the cessation program can be tested** to validate the true abstinence of participants to BQ chewing from the cessation program (Frankie AA, 2016 & 2022).

2.0 LITERATURE REVIEW

2.1 Global Epidemiology of Betel Quid Chewing

The distribution of BQ usage is about **10–20% of the world's population**. Globally, it is deemed about **600 million people** are indulging in this ill-habit of chewing BQ. Eventhough BQ usage is apportioned around the world, most of its users are concentrated in South and South-eastern Asia; including South-eastern China, Hainan Island and Taiwan, China, and the Pacific Islands. In certain areas such as the **Malay peninsula**, eastern and southern Africa, Europe and North America; the habit was brought in into those regions by migration of peoples from places where BQ use was prevalent. In the recent years, the **phenomena of BQ chewing practices has gained more attention in South Asia**, Taiwan and China due to the increasing and remarkable negative health effects reported among its users (Gupta & Warnakulasuriya, 2002).

In an intercountry prevalence study in 2011, Lee CH et al. claimed **the habit was utilised by different genders varyingly based on their demographics**. In Taiwan, Mainland China, Nepal and Sri Lanka, there were more males who practised the BQ chewing habits. And in countries like **Malaysia** and Indonesia; **females were the larger proportion who practised this BQ chewing habit**. The study too identified that low education level, alcohol consumption and tobacco smoking were significantly associated with BQ chewing.

Table 2.1 Intercountry Prevalence of Chewers in Lifetime & Current Chewers (Stratified by Gender) (Year 2011)

Prevalence	**Chewers in lifetime (%)**		**Current Chewers (%)**	
Gender	**Male**	**Female**	**Male**	**Female**
Taiwan	**15.6**	3.0	**10.7**	2.5
Mainland China	**29.0**	2.3	**23.9**	1.8
Nepal	**43.6**	34.9	**43.6**	34.9
Sri Lanka	**21.2**	14.5	**18.0**	13.5
Malaysia	10.3	**32.1**	9.8	**29.5**
Indonesia	12.4	**47.8**	12.0	**46.8**

Table 2.1 shows that the prevalence of female chewers were higher in both categories of chewers in lifetime and current chewers (32.1% and 29.5% respectively).

Table 2.2 Intercountry Prevalence of Proportion of New BQ Chewers and Past Chewers (Stratified by Gender) (Year 2011)

Prevalence	**Proportion of new users in chewers (%)**		**Past Chewers (%)**	
Gender	**Male**	**Female**	**Male**	**Female**
Taiwan	7.7	0.0	**4.8**	0.5
Mainland China	11.1	24.7	**5.1**	0.5
Nepal	13.1	18.2	**0.0**	0.0
Sri Lanka	15.5	20.3	**3.2**	0.9
Malaysia	**0.00**	**10.7**	0.5	**2.6**
Indonesia	14.7	**7.7**	0.4	**1.0**

***New users** defined as those who **uptake and use BQ regularly for ≤ 2 years**

Table 2.2 shows that 10.7% of females in Malaysia have uptaken the BQ chewing habit in the past 2 years in 2011. Malaysian females constituted the highest proportion of past chewers (2.6%) who claimed to quit the habit in the past 6 months or more (Lee CH et al., 2011). The reasons of quitting by the Malaysian females and the validity of their cessation response should be tapped into by researchers; to either emulate the 'success story' of quitting or to improve the validity of self-reported cessation outcomes with a better evaluation tool.

Table 2.3 Age Specific Prevalence of Malaysian and Indonesian Chewers (Stratified by Gender) (Year 2011)

Prevalence	**Age-specific prevalence (%)**			
Country	**Malaysia**		**Indonesia**	
Gender	**Male**	**Female**	**Male**	**Female**
≤ 30	1.8	4.7	1.1	18.9
31-40	3.0	28.8	14.4	35.9
41-50	16.2	49.1	17.4	61.2
51-60	**32.7**	**68.7**	**22.3**	81.5
≥ 61	20.0	61.3	20.0	**95.9**

Table 2.3 shows a comparison in age specific prevalence between Malaysia and Indonesia. Both of these countries were selected as they had a similar characteristics in the chewer's gender prevelance and demographics. Among the **male chewers, the most prevalent age group were of 51-60 years old** (Malaysia 32.7%, Indonesia 22.35%). Whereas among the female chewers, a slight difference was noted. In **Malaysia** the **most prevalent age group** for **female chewers were the age group between 51-60 years old (68.7%)** while in Indonesia, the most prevalent age group for female chewers were ≥ 61 years old (95.9%) (Lee CH et al., 2011).

In the same study, **patterns of BQ chewing** was observed. It was seen that **most Malaysian females practised chewing BQ risk habit singly (27.8%)**. Whereas a small portion of females combined it with other substances such as BQ with smoking (1.2%), BQ with drinking (0.4%) and BQ with smoking and drinking (0.1%). **Males in Malaysia mostly practised BQ chewing habit with smoking and drinking (4.1%),** followed by BQ chewing with smoking (3.8%) and BQ chewing with drinking (0.2%). Those chewing BQ singly were only 1.7% (Lee CH et al., 2011).

In general, the small prevalence of combined risk habit practice seen among Malaysian BQ users is advantageous to the nation's healthcare system as it may observe less synergistic negative effects of the combined ill-behaviours of BQ chewing, drinking and smoking in the country. Lee CH et al. (2005) in his earlier study claimed **BQ chewers who had more that one risk habits have a synergistic risk of contracting three cancers of the upper gastrointestinal tract (GIT)**; oral cavity, pharynx and esophagus (OR 8.1–41.2). The author too claimed there was a **greater cancer risk** observed in BQ users who **habitually swallowed the juice from AN chewing**. In Malaysia, only 4.8% males and 3.3% females claimed swallowed the BQ juice while practising this habit. An epidemiological study in Taiwan reported that **drinking and smoking are significantly associated with an earlier onset age for BQ chewing habit** (Yap SF et al., 2008).

Apart from that, Lee CH et al. (2011) associated **low education background as one of the contributing factors for BQ chewing habit**. Among the study sample, 61.2% claimed to have ≤ 6 years of education (primary education), 36.7% had 7–12 years of education (secondary education) and only 2.1% had ≥ 13 years of education (tertiary education). The authors further recommended countries like Malaysia and Indonesia to increase the amount of educational and

promotional materials in regard to BQ chewing topics (health and disease) to increase awareness and empower the females from taking up this habit. The authors **categorised the females in both countries to be in a high risk group for BQ chewing**. These findings were supported by Javad F et al. (2010) where he observed the BQ habits were more prevalent among the study participants of poor education background and in females.

A **nationwide promotional campaign** such as December 3 ‘‘Betel Quid Prevention Day” was initiated in 1998 and was observed to be successful among the male chewers to quit the habit. A high rate of BQ cessation was noted (31.1%) among the Taiwanese males after such promotions. The authors too recommended to incorporate smoking and alcohol cessation strategies in the BQ national policies to have a more promising outcome.

Gaining an in-depth understanding on the aspects of gender, age- specific categories and patterns of BQ chewing behaviours and success stories of cessation in other countries are very valuable in our efforts of adapting a cessation program for the Malaysian high-risk group.

2.2 Worldwide Accessiblity of BQ products

Since the advent of machine-manufactured BQ, now **BQ has become more accessible** from different parts of the world by all categories of people. The **advancement of telecommunication** have paved the way for BQ’s sale advertisement to reach countries where BQ habits were not practised. For example, the sale of ‘paan masala’ in India can be purchased in the United States of America through the e-Bay platform. This **enables the BQ users to maintain their habits even though after migrating to western countries** such as the United States, United Kingdom or Australia where the BQ habit is not practiced or the fresh preparation of BQ is not available (Little MA et al, 2015).

2.3 Reasons for Betel Quid Chewing

To date, there is **no published study** on the assessment of reasons for BQ chewing in Malaysia. There was an unpublished study participated by Universiti Malaya (Herzog T et al., 2014) that stated 'friends' and 'family' were the greatest influence for Malaysians to commence BQ habits (42.2% and 32.3% respectively). Another reason was 'readily available BQ around the house' (9.3%) promoted the said behaviour.

More than half stated that the reasons they kept their BQ chewing practise were due to the influence of 'most of their friends that chewed' (54.7%), 'they liked the taste' (53.1%) and 'they liked having something in the mouth' (51.2%). Others claimed having kept the habit 'as part of their culture' (47.2%) and claimed 'people did not respect them if they didn't chew BQ' (8.5%). The participants too added 'chewing BQ was an important social event' when hanging out with friends (40.5%), at home with family (37.1%) and in weddings (33.6%).

In Tahir Z et al. (2003), the authors found most of the villagers in Kampung Siasai, Kota Belud (n=175) practised BQ chewing mostly due to 'the good feeling' it gives chewers (59.8%) and for 'socialising' (51.4%). Other reasons noted by the authors were 'for fun' (12.6%), as a 'cultural norm' (12%), 'as part of personal beauty and cravings' (2.9%) and for 'strengthening their teeth' (1.7%).

In 2014, Little MA et al. developed **Reasons for Betel-Quid Chewing Scale (RBCS)**; a standardized instrument to assess the reasons why individuals chew betel-quid. There was 3 domains to assess the reasons for chewing: namely **reinforcement,**

social/cultural, and stimulation. The reasons portrayed in Herzog T et al. (2014)'s unpublished study were the few items comprised in the first and second domains for this scale.

Murphy KL et al. in 2022 concluded that the RBCS was a valid and reliable tool to measure the reasons for chewing BQ across different genders and different type of chewers as its items were moderately and strongly correlated to each other.

2.4 Factors affecting BQ chewing habit initiation and cessation in Malaysia

2.4.1 Initiation Factors

Ghani et al. (2011) performed a nationwide study among patients with oral mucosal lesions patients from 14 states in Malaysia to further assess the factors of initiation and cessation of BQ habits. She and her team found out that **being a female** from **Indian ethnicity** or from **indigenous part of Sabah and Sarawak** and who were **above 40 years of age** had a higher likelihood to develop BQ chewing habits. She too claimed having a habit of **smoking** was significantly associated to developing BQ habits among Malaysians.

In 2019, Ghani et al. performed a study to elucidate the ethnic variation among Malaysians who practiced oral cancer risk habits. They further found a **similar high prevalence** of BQ chewers among people **of Indian ethnicity** (45.2%) and **Indigenous people** (24.8%).

The **trend of more female chewers in a country** is also evident in other South-east Asian populations such as among the Cambodians. The reason why more chewers in Malaysia are female can be comparable to a study finding from Taiwan (Yap SF et al., 2008). The study

stated that most female chewers are **housewifes staying in plantations** and were from **low socioeconomic backgrounds** where they too **faced boredom, financial and social problems** in their family. They **encountered peer pressure** to take up the BQ chewing as this habit is a **traditional culture** in certain society. The high prevalence of Indian BQ chewers was also similar to the study findings of Hirayama et al. (1966).

2.4.2 Cessation Factors

In terms of cessation factors of BQ habits among Malaysians, Ghani et al. (2011) mentioned cessation was seen to be more common among the **male gender** and the **Chinese ethnicity**. In addition, the frequency and type of betel quid chewed also played a role in the BQ habit cessation. Those who **chewed less than 5 quids per day** and those who **didn't include AN or tobacco in their quids** were more likely to stop BQ chewing habits.

Cessation was common among male and females of **Chinese ethnicity** as this habit is **rare in the Chinese culture**. Thus from the environmental perspective, quitting BQ in a Chinese society or neighboorhood is more conducive and successful. A study showed that the **foul-smelling breath shuns the younger generation from incepting this behaviour** (Ghani et al., 2011).

In regard to chewers who are also current smokers, BQ cessation was seen to be more difficult. A study in Taiwan claimed that it is **twice more likely for an ex-smoker to quit BQ chewing than a current smoker**. Surprisingly, **current smokers are 10 times more at risk to take up BQ chewing habit if they haven't in Taiwan**. Thus, BQ chewing cessation is less likely and more difficult in a smoking population (Ghani et al., 2011).

As for the frequency of quid chewing, a study in Taiwan, Lin et al. (2002) observed that chewers who **chewed more than 5 quids per day were less likely to quit on their own**. This phenomena can be likened to nicotine dependency syndrome among smokers. BQ chewers too experience **arecoline dependency syndrome**, thus a natural or casual cessation among chewers who utilise more than 5 quids per day is less likely due to a greater level of dependency.

The study claimed **poor awareness and knowledge of the hazardous effects of BQ carcinogens** to general health and oral health of chewers played a role in the uptake of this habit. And once they are in a 'dependent' state, they are unable to let go of the habit by their own. Thus, the author urged to drastically amplify educational efforts in the high risk groups to promote health and cessation of habits (Ghani et al., 2011).

2.5 Dependency syndome among Malaysian chewers

Lee CH et al. (2012) stated dependency syndrome among BQ chewers in 6 Asian countries including Malaysia was **linked to gender, age, schooling years, drinking, smoking, tobacco-added BQ use and environmental accessibility** of BQ. During this study, the BQ prevalence among Malaysian was 39.3%. **Female dominated** the BQ prevalence with 29.5% whereas male's BQ chewing prevalence was at 9.8%. As BQ habit was widely accepted and faced no social and public constraints such as for smoking and alcohol drinking, author urged to not overlook the BQ issue due to this matter.

The study reported that most of the Malaysian chewers were **above 40 years old** (86.7%; Female-61.1%, Male-25.6%). The BQ chewing prevalence was seen positively correlated with age and the BQ dependency was related to older age group participants. **Low**

educational level (schooling years of 6 years or lesser) possessed a greater risk for chewers to experience dependency syndrome (adjusted OR 27.2). Those who **concomittantly practised** other risk habits such as drinking alcohol were seen to be more likely dependent on BQ chewing (adjusted OR 9.4). Whereas smoking was linked to a lower probability of BQ dependency. Tobacco-incorporated BQ chewing was inversely correlated with tobacco smoking (r =70.17, *P*<0.001) (Lee CH et al., 2012).

The **amount and frequency of BQ consumption** were significant predictors of dependency among Malaysia chewers (OR 1.3 and 1.8 respectively). **Tobacco-added BQ** conferred a 1.3-fold higher risk of dependency than tobacco-free BQ. The study found that the BQ dependency (DSM-IV prevalence 7.7) among Malaysian women participants exceeded the reference DSM-IV prevalence of alcohol dependence reported in several national surveys worldwide (1.2–4.4%). The **highest dependency symptoms** seen among Malaysians were **cravings, withdrawal symptoms and continued use despite problem** (Lee CH et al., 2012).

Pankaj C. (2010) stated feasible **environmental access** to BQ is a sociological concern especially if BQ is readily available in a person's surroundings; as it is closely associated with its use. The study showed that there was four environmental promotion factors found in Malaysia; **easy availability, low cost, ready-made packaging and attractive packaging** and **no preventive activities reported in the country**; namely BQ-related ban, statutory warning and health education awareness programmes. Only Taiwan had practiced all the 3 preventive activities evaluated in the study (Lee CH et al., 2012).

Approaches such as Diagnostic and Statistical Manual of Mental Disorders (DSM; American Psychiatric Association, 2000) and the ICD-10 (World Health Organization, 1992)

were the common tools used in dependency studies for BQ. Both tools only involved the generic assessment of dependence among the BQ chewers.

In 2012, Lee CY et al. developed and provided an initial validation for the first instrument designed specially for measuring the BQ dependence; the Betel Quid Dependence Scale (BQDS). The BQDS was comprised of 3 domains; physical and psychological urgent need, increasing dose and maladaptive use. The instrument had a good internal consistency (α=.92) and construct validity. Good construct validity represents how well the ideas or theories are translated into actual programs or item measures. Nevertheless, there was limitation to this first scale as it was developed among male prisoners who had history of BQ chewing before being incarceration in Taiwan prisons and items was evaluated in Chinese language. In 2014, Herzog TA et al. replicated and extended the validation research on BQDS among English speaking male and female current chewers in Guam.

Guam is an island in Micronesia which was situated close to Philippines and East Malaysia (Figure 2.1). Due to their proximity, they shared similar cultural history and tropical marine climate. Thus, this BQDS scale can be utilised to evaluate the dependency level among BQ chewers in the high risk group in Sabah for this study as they share some similar characteristics.

Figure 2.1 Map of Guam and Its Proximity to East Malaysia

2.6 Readiness to Quit Habit among BQ Chewers

From an unpublished study participated by Universiti Malaya (Herzog T et al., 2014) among Malaysian BQ chewers regarding their willingness to quit the habit, 29.2% of the participants felt they should quit but claimed were not ready and 29.3% reported a reduced amount of quid (s) that they chewed. Whereas 20.3% participants were not considering to quit at that moment and 20.6% wished they had never started chewing BQ in the first place.

The mean time of **quit attempts** made were 2.0±3.2 times. The most common methods used for quitting among the participants were self motivation (40.1%) and through cold turkey (19.7%). **Health concerns** were specified as the main reason for quitting the chewing habit (77.3%). Only 3.9% chewers who included tobacco in their quid managed to quit, whereas 96.1% of others who included tobacco in their quids were struggling with the habit and were current chewers. **Inclusion of tobacco into quid** made the BQ quitting

experience more challenging and less successful. Likewise, among chewers who rated that **chewing was an important social event** when hanging out with friends, 96.0% of them were current chewers and only 4.0% were ex-chewers.

Among the participants who were **ex-chewers**, 65.3% were very confident that they will remain as non-chewers, while 31.3% were not sure whether they had quitted the habit for good. Close to quarter of them (22.7%) reported that they will definitely take up the chewing habits again someday.

2. 7 Barriers in Quitting BQ Chewing Habit & from Joining a Cessation Program

Sotto PP et al. (2020) conducted a qualitative study to explore the barriers inhibiting chewers from quitting BQ chewing and from participating in a cessation program in order to improve the delivery of future cessation programs. Their study was unique as the study incorporated non-chewers in addition of chewers to gain more wholesome inputs about the barriers faced by the chewers individually and in the commmunity. The authors reported **3 main domains that highlighted crucial reasons** why a BQ habit could not be broken.

Firstly, in the aspect of **sociocultural influence (SCI)**. In the study, SCI was defined as the "interactions between an individual and members of their community, and the beliefs and attitudes that they manifest through socializing and relating in that culture". Sotto PP et al. (2020) found that **communities perceived chewing AN as an harmless act** and **claimed only cigarette smoking was harmful**. The chewers themselves too believed that they would not develop any cancers or were not at risk of it as they saw their grandfathers who were still healthy until 80 years of age.

They claimed chewing was **part of their culture** and it was an **expected social interaction** when gathered with families, friends and social groups. AN is oftentime offered as a **welcoming gesture** from a host to a social group **to stimulate conversation**. Apart from that, they claimed chewing AN until it stains their teeth can strengthen the teeth. They too believed the phrase "**there is wisdom in the basket**"; which portrays that when a person searches for the BQ in the basket, it buys them time to think for answers or on how to respond in a situation (Sotto PP et al., 2020).

Apart from that, since the community did not perceive the seriousness of the habit, they **received support from family members and their superiors** which in return created an enabling environment for chewers to continue their habits. For instance, they are not reprimanded when they chew at home. And when at workplace if the chewers face any difficulty, their bosses provided them with money to purchase AN to prevent work interruptions (Sotto PP et al., 2020).

From the non-chewer (NC)'s perspective, the NC felt if chewers were **more socially familiar with the facilitator** of the cessation program, they will be **more likely to join it**. NC proposed **incorporating ex-chewers into the cessation program** as the difficulties faced by the ex-chewers and how they overcamed that ill habit could be very helpful and relatable to the current chewers (Sotto PP et al., 2020).

The second domain of barriers relates to the **Behavioral Influence (BI).** In the study, BI was defined as the "sensations experienced while chewing an AN and the actions in response to these sensations". Chewers mentioned that **AN helped them to be more alert and function well throughout the day**; especially at night. As some chewers are required to work overnight, they claimed **chewing AN is better than taking any energy drinks and helps them stay**

awake. Apart from that, they claimed AN gave them a sense of euphoria and some relaxation. A chewer claimed AN gave him 'a high that only AN can provide'. Another chewer claimed **chewing AN gives him a chance to sit and take a break** (Sotto PP et al., 2020).

Besides that, some **claimed chewing BQ has become their daily routine**. As soon as they arose in the morning or after taking a meal, the chewers needed a fix of a BQ. Some chewers felt **BQ habit did not portray high dependency but rather was a routine reinforcement**. However, some claimed they were addicted to BQ chewing. They claimed they **had compulsive desires to chew that led them to sporadic engagements** which in return made them hard to stop the habit. They advocated this as a reason they could not quit chewing BQ and 'it had become part of their life'. They remarked that 'once anyone had known the taste of AN, it was hard to be detached from it' (Sotto PP et al., 2020).

The third domain relates to **accessibility**. In the study, accessibility was defined as the ease of getting and chewing AN, the ease of obtaining a readily available information about BQ adverse effects, and the ease to attend a cessation program. There was no advertisement on the detrimental effect of BQ chewing. Most consequences seen by the public were regarding cigarette smoking. The lack of information propagated the BQ risk habits to stay longer in the community (Sotto PP et al., 2020).

There was lack of awareness noted in the aspect of need for a cessation program by the chewers. They **presumed that they were capable of quitting this habit by themselves without any formal guidance**, thus **they did not appreciate the availability of a cessation program** in their community, for example, in the Island of Guam. Apart from that, the NC advised for the **content of cessation program to be basic** as most of the participants can only understand the elementary level of language and counselling therapies. Cessation programs

were held during daytime which were also the working time of the chewers, thus they claimed to face **time and transportation constraints** (Sotto PP et al., 2020).

Sotto PP et al. (2020) came up with excellent suggestions to improve future cessation programs. Firstly, **to educate the community on the adverse effects of AN especially on its carcinogenic properties** to break their beliefs and perceptions that AN is harmless. As the BQ chewing habit is ingrown into the next generation as a proud racial habit and through communal upbringing, **adequate preventive knowledge and awareness could hamper the habit transition to next generation.** By being aware of the health consequence of BQ chewing, the chewers could be **empowered to overcome the fear of social consequences** in a community associated with quitting. **Partnership with the public health officials** could be garnered to launch health campaigns within the community.

To increase participation from working adults, the **cessation program could be made portable and be incorporated into the working schedule of the chewers**. A collaboration can be attained with the managers of the industries; which are often the plantation estates managers. In addition, **inclusion of facilitators of a similar social group** could help to gain the patient's trust and comfort during the cessation program and increase participation. Apart from that, **adverse effects of BQ could be incorporated in the education curriculums** in the schools to educate the adolescents to not take up the ill-health behaviour (Sotto PP et al., 2020).

In 2015, Moss J et al. conducted the **first cognitive-behavioural BQ cessation program** and faced few difficulties. The initial difficulty faced by the researcher was that some **participants were not interested in the cessation program** which made the program to be relocated to another island. Those in the new island were having high **motivation to quit** to **improve their teeth and mouth appearance and to save money**. Research staff sought the

village mayor's approval and help to encourage village participants to attend cessation program from his leadership position. Participation rate improved with **incentive providence**. This lured the family members and extended family of the participants to join concurrently the cessation program that was held.

Another barrier faced was **lack of participant recruitment due to lack of awareness of cancer association with BQ habits**. A similar finding was seen in a study by Paulino et al. (2011). They only perceived that tobacco addition into BQ might cause cancer. Thus, public education regarding carcinogenicity of BQ could motivate and increase partipation in cessation programs (Moss J et al., 2015).

Transportation was also seen as a barrier in the cessation program. Due to participant's eagerness to recruit their family members, they came carpooling with already participating group members without prior scheduling with program coordinators. This impacted the program and program was later changed into a walk-in arrangement cessation program. Thus, for future cessation programs, if family members were incorporated, **transportation should be ideally provided or cessation program should be held in the vicinity of the community** (Moss J et al., 2015).

Family dynamics was another barrier noted while recruiting participant's family members. Due to the role of family leader, the **males spoke more in the group discussion** and the females contributed lesser. As they came together with their children, sometimes the **children distracted their parents** in the cessation sessions. Thus, the **role of the facilitator is crucial** to ensure equal contribution and participation in the group discussion. A **chaperone** can be assigned if family participants are expected in the cessation program (Moss J et al., 2015).

Moss J et al. (2015) claimed during implementation of the program, many useful **inputs for individual chewer's improvement** were gained. As BQ chewing is a social process, the chewers needed to strategically **make changes to their existing relationship** with friends, co-workers and relatives. They avoided friends to escape the temptation to chew. They avoided workers by taking different lunch breaks to steer away from being teased or ridiculed during the process of quitting. **During family functions, they prefered to play with the younger generation of the relatives**; such as nephews and niece; as most of the older relatives would be indulging in their BQ chewing behaviours. Apart from that, they **created ready-made excuses** such as having cold sore, sore gums or wanting to save money to shun away the chewing invites. The chewers proposed **to invent an artificial AN** to fake chewing when they are among their social groups.

For the **improvement of the cessation program**, the chewers recommended to have an **informal group to provide social support** for group members during the process of quitting. The chewers too suggested **for inclusion of ex-chewers into the formal support groups** to learn from practical, real life experiences faced in the journey of quitting. **Inclusion of sports activity** such as volleyball and softball games into the cessation program was highly recommended as it not only would increase the social support strength, but also help the participants to deal with their cravings in a healthier way. As BQ chewers are from a lower socioeconomic background, they **disagreed with the concept of rewarding oneself with the money saved from abstaining chewing** as it defeats the original purpose of saving money for the chewers. Thus, this concept of motivation should be used with caution (Moss J et al., 2015).

Moss J et al. (2015) stated to tackle the **language barriers**, the cessation team should be equipped with **staff who are conversant in the comunity's local language well**.

Translating cessation materials to the local language will be advantageous in aiding chewer's comprehension and cessation.

Many participants claimed to have increased apetitie after quitting which led them to consume more food and experience weight gains. Participants too sometimes consumed unhealthy food such as ice cream and chips to ease their chewing cravings. Thus, **education regarding healthy and balanced diet and regular exercise** should be incorporated into the cessation program as a means to manage withdrawal symptoms (Moss J et al., 2015).

2.8 WHO's Framework Convention on Tobacco Control (FCTC) Policy

In 2003, World Health Organisation (WHO) organised a global convention to discuss solutions to combat the issue of tobacco that plagues the citizens of the world and they produced a framework called '**Framework Convention on Tobacco Control** (WHO FCTC)'. This framework has guided many tobocco-related regulations in Malaysia and also in other countries around the world. There are 4 articles of FCTC that can be applied to control BQ chewing practices in Malaysia.

Article 6 supports **imposing or increasing the taxation of BQ sales to reduce the purchasing demand**. In Taiwan, they have adopted this measure in addition of imposing taxes on cigarette sales alone. This was found to be more successful in reducing AN utilisation. In Malaysia, since BQ preparation is made fresh within certain communities, taxation is unfavourable to be imposed to the villagers. But similar taxation could be enforced towards online sale of BQ. As of 31st July 2022, there was BQ sale in Alibaba.com and Lazada.com platforms that could be readily accessed by all ages groups of Malaysian. This 'easy access' to BQ should be hindered by the relevant authorities by imposing certain taxation to curb its online sales.

Article 8 advocates **enforment of public areas protection** policies. In countries like Myanmar; employees are banned from chewing BQ during office hours and in Taiwan and Papua New Guinea a 'spitting fine' was enforced to protect its public places. In Malaysia, the BQ chewers normally chewed within their house or community vicinity and prepared a container in advance for disposing their red-stained saliva. Thus, the public places in Malaysia are yet to be contaminated with BQ stains. Nevertheless, village mayors could be notified of such policy; that betel-stained saliva should not be spat in public areas.

Article 13 advocates **educating the public about the consequences of BQ chewing** in mass media such as national television and radio programs. This has proven to produce increased awareness, heightened motivation and greater cessation intention and behaviours among the BQ users. In Malaysia, a brief 'air-time' of BQ preventive message in regard to association of AN to cancer causation could be televised during the peak hours of news streaming. This is a valuable initiative as female housewifes loves to fill their time by watching the television news or hearing the radio daily. Apart from that, a more successful platform to impart knowledge and awareness is through engaging the district health teams to personally venture into the high risk communities for educational programs. Interactive talks and presentation can be conducted. Real pictures of patients with cancer secondary to BQ chewing habits can projected to intensify their intentions to quit the behaviour. Health promotive events should not only be focussed throughout Mouth Cancer Awareness Week (MCAW) but also periodically among the communities with this high risk behaviour for a timely awareness and to intercept this behaviour.

Article 14 describes about **reducing demand for tobacco**. This has led to 'gutka' product ban in most states of India in 2016 and a blanket ban in Papua New Guinea's capital;

Port Moresby in 2013 in the effort to make sure its capital is clean from BQ juice spitting. In Malaysia, alternatives can be considered to ban the online sale of BQ products in this country.

Article 14 too **promotes cessation programes** to the local community. Cessation programs are very crucial to help BQ chewers to stop this behaviour. Similar to cigarrete smoking, without counselling or pharmacological aids, smoking behaviour is not easily reversed. Since BQ chewers mostly suffers from dependency syndrome, a cessation program is a necessity to guide them to quit this behaviour.

2.9 Cessation Programs

A systematic review conducted by Das et al. in 2020 reviewed BQ cessation interventions from 1990 till 2018. Only 8 papers were reviewed indicating a lack of research or publications in this field of study. Most study findings recommended cessation interventions to be culturally adapted to its local community to increase program acceptance and participation (Croucher et al., 2012).

Siddiqi K et al. (2016) conducted a study to assess the effect of smokeless tobacco (SLT) cessation on South Asian population. As South Asians are the major utilizers of SLT in the world, this research was initiaited to add onto the body of evidence and aid future cessation interventions. The authors developed a Behaviour Change intervention (BCI) which included 23 activities and an interactive pictorial resource that supported the activites. The activities were directed to raise awareness of harms of SLT, benefit of quitting, increasing participant's motivation and self-efficacy, developing effective strategies to manage urge or triggers to chew and withdrawal symptoms as well as relapse. BQ was one of the most used SLT concoctions by the participants and on a long term follow-up (6-months), 12.5% achieved cessation (4 out

of 32 participants). This study concluded that **participants were receptive to the culturally-adapted health messages** and BCI aided more in participant's reduction of risk habits compared to complete cessation. The **compelling negative portrayal of SLT users** and captivating graphic images of the harmful health effects of SLT use was effective in generating emotive response and intention to quit and as well to bust the myth and challenge the social belief towards this risk habits. The study highlighted the need for additional training for BC techniques, intergrating nicotine replacement therapy into the BCI to increase motivation to quit and reducing duration for pre-quit session as most participants may have less time to spend for the intervention. The author added that by conducting this intervention, it helped to tackle the health issue that has plaqued the women of a minority ethnic group in the United Kingdom. This intervention addressed the health inequalities present in this minority and offered opportunities for the authorities to engage with these marginalised communities.

Raja et al. (2014) performed a randomised control trial to educate tobacco users on the harmful effects of the habits and to effect behaviour change to the participants in a tobacco cessation centre in Lucknow, India. He randomised 40 qualified study subjects into 2 groups; intervention group that utilised Cognitive Behavioural therapy (CBT) for effecting change and a control group that was exposed to a Basic Health Education (BHE) model. Most of the participants were males who stayed in rural areas, who had completed high school education and most of whom had consumed more than 10 sachets of pan masala daily for an average of 10 years. Prior recruitment, colourful posters regarding information of free cessation program was advertised in public areas. During the program, participants in the intervention group was guided to overcome barriers to cessation, their quitting self-efficacy was enhanced, the inputs from previous quit attempts were learned, and their risk perceptions and pros and cons of quitting were discussed.

In whole, the CBT provided education, encouragement, support and equipping participants with coping skills and was repeated and emphasized at every follow up. Whereas in control group, participants were provided information regarding the harmful effects of tobacco use and were advised to be mentally positive, to be busy or occupied, to remove tobacco products from their surroundings, to listen to music and to exercise. All the motivational information were repeated at every follow up for the control group. At post 1-month, the study mentioned **intervention group (CBT) yielded better success rates in BQ cessation compared to a BHE talk or module alone**. The author stated CBT for BQ risk habit **can be remodelled after a smoking cessation** CBT. And the study concluded that any intervention (either CBT and BHE) given to motivate participants to quit risk habit is indeed helpful (Raja et al., 2014).

In countries like India and Pakistan, BQ chewing issue has been tackled from the adolescent age period itself due to the high consumption among the younger segment of their population. Mall ASK and Bhagyalaxmi A (2017) conducted a clustered randomised control trial among 20 government schools in rural Gandhinagar, India. Adolescents were chosen as the population of interest for the study as Indian youths were the second highest consumers of tobacco in the world after China in a Global Youth Tobacco Survey (GYTS) in 2009. As adolescence period is a crucial period wherein the adolescents would be intuitive and experimentative to explore new things and the authors mentioned once the adolescents are addicted to pan masala (BQ with flavourings), they are more likely to get addicted to other tobacco products in the future. Thus, the study targeted to impact a change of behaviour among the adolescents. As peer pressure was one of the contributing factor among adolescents to uptake the tobacco-related habits, a peer-led intervention was decided as the best mode of delivery for this intervention. The study modified a school-based, peer-led intervention; A Stop Smoking in School Trial (ASSIST) which was designed in United Kingdom, to intervene the

smokeless tobacco users among adolescents in this study. The consumption of pan masala in intervention and control groups was 46% and 40% at baseline. They were only 1-2% of participants who were smoking. Close to half consumed tobacco on a daily frequency (49%), mostly initiated habit around 11 years old and admitted their parents too practiced smoked and smokeless tobacco habits. After implementation of progrm, the consumption of pan masala reduced significantly after 1 year; from 46.3% to 35.8% in the intervention group and from 40% to 33.7% in control group. The odds ratios for students who consumed pan masala was 1.4 (post 6-month follow up) and 1.1 (post 1-year follow up). This study strongly suggests that intervention had beneficial cessation effect on adolescents.

Hussain et al., (2018) performed a clustered randomised controlled trial to improve adolescent's knowledge about the deleterious and harmful effects of SLT and BQ, change their perceptions and to encourage them to quit the behaviour. The study was conducted among 2140 adolescents from 26 private and public-sector schools in Karachi, Pakistan. Adolescents became the population of interest again in this study as during 2004 to 2013, the chewing prevalence of SLT among adolescents substantially increased from approximately 7% to 15% in the South East Asian Region (5.3% were current SLT users and 11.2% non-tobacco users but were susceptible to tobacco use in future among youths in Pakistan in 2013). The intervention group were exposed to Behaviour Change Intervention (BCI) to motivate the young users (11-16 years old) to quit SLT practices inclusive of BQ practise with and without tobacco. The BCI components included identifying the SLT and BQ products and their harmful effects, the importance of setting a quit date, preparation towards quit date and management of triggers and recognition and management of withdrawal symptoms.

Upon implementation of program, in the **aspect of SLT cessation**, 29% ceased their habit and consumption rate was reduced from 44.7% to 11.6% in intervention arm, whereas

8% ceased habit and consumption rate was reduced from 40% to 25% in the control arm. In the **aspect of knowledge and awareness** towards harmful effects of BQ products, knowledge improved from 78% to 97.2% in intervention group and from 80.3% to 96.9% in control group. Improvement of knowledge was seen in understanding SLT and BQ products as causative for oral cancer and understanding of malignant transformation of oral white patch/lesions. In the **aspect of harmful perception of SLT and BQ** improved from 78.3% to 91.3% in intervention group and slimly 75.7% to 76.6% in the control group (Hussain et al., 2018).

Hussain et al., (2018) concluded the role of BCI was promising in improving adolescent's knowledge and perception positively. They too claimed convincing results can be achieved if BCI is tailored with the emphasis on the identification SLT products commonly used by adolescents, highlighting the ill effects and teaching students how to quit and manage the triggers and withdrawal symptoms. Authors too recommended including BCI into school curiculum, to create SLT and BQ free schools in future.

Siddique & Mitchell (2013) stated **portraying the negative effects of BQ chewing through captivating and vivid visual images** could make the cessation program more effective. Wang et al. (2007) added that educational interventions should be **reinforced after a period of time** to encourage total cessation and abstinence from the BQ habit.

2.10 Betel Nut Intervention Trial (BENIT)

Paulino YC et al. (2020) embarked on an **evidence-based cessation program**. BENIT is a randomized, controlled and superiority trial with 2 parallel groups of equal sizes **designed to test the efficacy of BQ cessation program**. This trial was developed by University of Guam with the partnership of University of Hawaii Cancer Center. It was conducted in the island of Guam and Saipan in Hawaii and also incorporated BQ chewers who added tobacco into their quid.

BENIT is a **cognitive-behavioural therapy program** that was remodeled after a group-based smoking cessation program. The **cognitive component** of the BENIT framework addresses the chewers' attitudes and beliefs about betel nut chewing. For example, most studies revealed the participants generally have lack of knowledge and underestimated negative health effects of BQ. **Behavioral component** aims to replace chewing-promoting behaviors with behaviors that are more conducive to quitting BQ and staying quit. It also includes preparing responses for social situations where the pressure to chew are likely to occur.

The **intervention group** consists of 5-sessions which spans over 22 days, with an additional follow up session after 6 months. The sessions use betel nut cessation social support groups, as well as an interactive discussion on how to quit chewing. An educational betel nut cessation booklet too is provided. In the **control group**, minimal interaction was employed between participant and facilitator regarding the cessation strategies. Participants was only be given a betel nut cessation booklet. Both groups were required to provide saliva samples.

The **Betel Nut Cessation Social Support Group** is led by trained facilitators over a 22-day period. **Session 1** (Day 1) covers a thorough discussion of adverse health risks related with BQ chewing, and introduction to self-monitoring and triggers logs. **Session 2** (Day 8)

involves a review of their logs, and discussions of lifestyle changes to assist their BQ cessation. **Session 3** (Day 15) will be the quit day for chewers. Coping mechanisms and plans to maximize social support will be elaborated. **Session 4** (Day 18) will focus on participant's quitting experiences. Facilitators will also review the negative health effects when participants crave to chew again. Discussion on quitting experiences will continue in **Session 5** (Day 22). Facilitators will assist those who have relapsed episodes and teach them how to manage it.

Betel Nut Cessation Booklet is a single booklet that encompass all the information offered in the experimental group, minus the social support sessions. The booklet was given to the participants individually by study staff at a designated office in Guam or Saipan. There were three assessments for them to complete at baseline, 22 days, 6 months.

Questionnaire was administered at Day 1, Day 22 and Month 6 to obtain demographic, chewing status and frequency and willingness to attend intervention group sessions to both groups. Intervention group would receive **topical homework** to reinforce themes explained during the therapy session.

2.11 Saliva Biomarkers of Areca Nut

Nair J et al. (1985) was one of the first researchers that studied the exposure of tobacco-specific and areca nut-specific N-nitroso compounds in saliva among BQ chewers who incorporated tobacco and without tobacco. The study found arecoline (AN specific alkaloid) at high levels in the saliva of both type of BQ chewers; with or without tobacco. Nicotine and cotinine were also present in the saliva of BQ chewers who added tobacco.

Huang JL et al. (1989) developed a simple and rapid method to simultaneously determine the 4 major alkaloids in AN which was the high-performance liquid chromatographic (HPLC) determination. Through this method, the author concluded that all four major levels of AN alkaloids can be determined and was higher than the previous study. The study used fresh AN as sample.

Franke AA et al. (2015) performed a chemical analysis study to identify saliva compounds which were specific to the 3 most common preparations of AN used in the study site (Guam); red, matured areca nut only (BN group), red, matured areca nut wrapped in betel leaf (BL group) and green, young areca nut wrapped in betel leaf, slaked with lime and incorporated with tobacco (BQ group). The study showed the **predominant compounds in saliva from those chewing AN were guvacine, arecoline, guvacoline, and arecaidine** and the predominant compound in the betel leaf and saliva from those chewing the leaf was chavibetol.

Guvacine levels were 6 times higher in the matured AN extracts compared to young AN extracts (1, 871.4 ug/g vs. 302.9 ug/g) whereas **arecaidine levels were 2 times higher in the young AN extracts** compared to the matured AN extracts (93.2 vs. 47.7 ug/g). **Chavibetol was the main constituent** of and were exclusively found in the **betel leaf**

extracts at a concentration of 39,873.8 ug/g. **Nicotine was the major alkaloid in the tobacco extracts** (15,454.8 ug/g) with a slight amount of it detected in the AN and leaf extracts (0.1 – 1.4 ug/g) (Franke AA et al., 2015).

Franke AA et al., in 2016 conducted a pilot study to further explore the pharmacokinetics of AN's alkaloid as those assessment of biomarkers was very in need to evaluate the effectiveness of BQ cessation program that was targeted to reduce the oral cancer burden in the high-risk areas in Hawaii. The study found that AN alkaloids; **arecoline, guvacoline, guvacine, and arecaidine were detected in saliva of all participants** and **peaked within the first 2 hours post-chewing before returning to baseline levels after 8 hours**. The salivary chavibetol was reported in participants consuming betel leaves in their quid and it peaked 1-hour post-chewing. Thus, the study concluded the AN biomarkers from saliva can be followed up only on a short-term basis (⩽8 h post-chewing). The study too claimed to find similar AN alkaloids from urine samples of the participants.

Franke AA et al. (2022) reported that **saliva bio verification results are valid to be used to verify the self-reported chewing status of participants ('quitter' or 'chewer') at day 22 follow-up to evaluate cessation program's effectiveness**. In the BENIT trial, among the quitters, the decrease in AN compounds were most significant for arecoline ($p=0.044$), followed by arecaidine ($p=0.042$) and nicotine ($p=0.011$). Among the current chewers, the significant decrease was noted only for hydroxycotinine ($p=0.004$).

2.12 CONCEPTUAL FRAMEWORK

The conceptual framework for this study is as below:

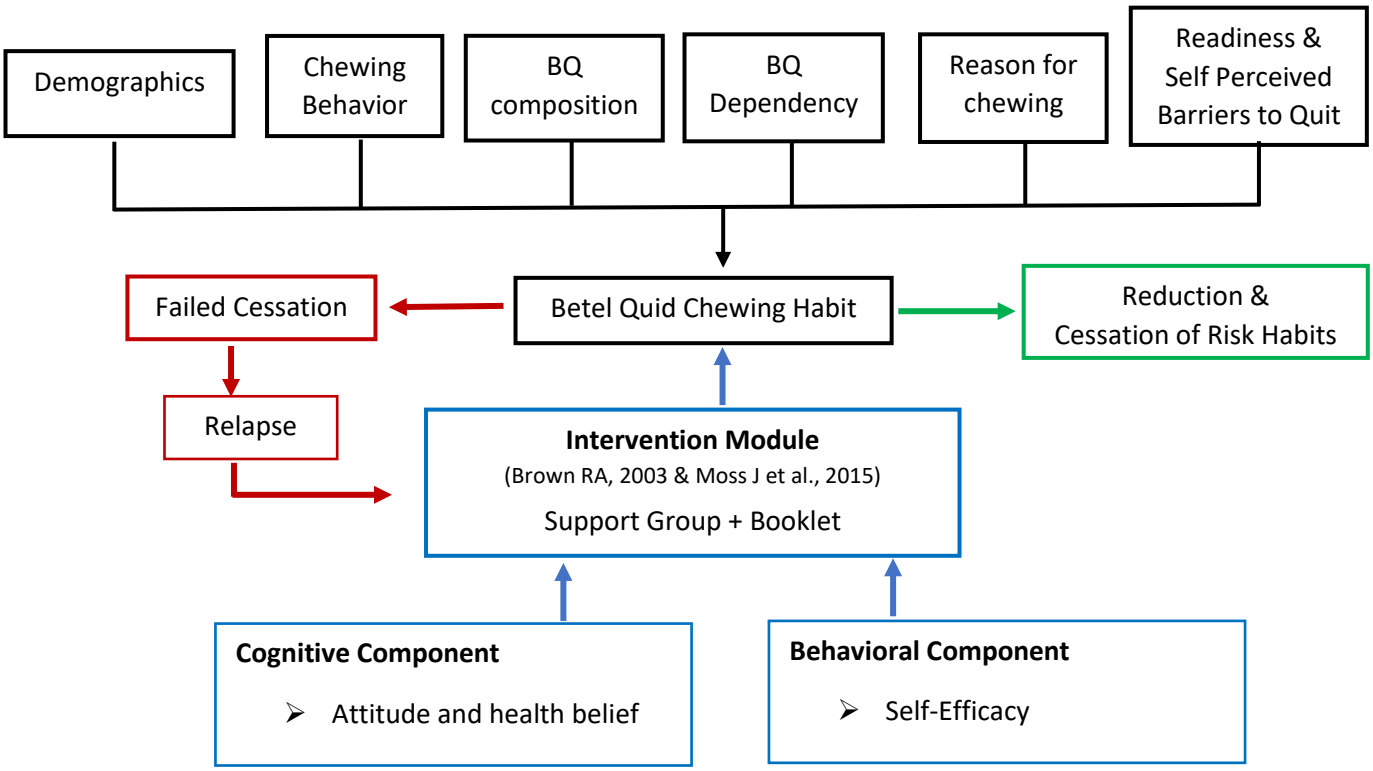


Figure 2.2 Conceptual Framework of the Study

Assessment of participant's demographics, BQ chewing behaviours, BQ composition, BQ dependency levels, reasons for chewing, readiness and self perceived barriers to quit habit are the cornerstones of a BQ chewing habit. They are important determinants of a participant's ability to quit the behaviour. After selecting the qualified participants for the intervention group, an intervention module which was developed by Brown RA (2003) and tested by Moss J. et al. (2015) will be used as the intervention of choice in this study.

The **general framework of the intervention module** is based on the cognitive behavioral therapy which aims to assist chewers to quit risk habit with structured intervention sessions. The **cognitive component** tackles the chewers attitude and health beliefs; for

example by educating participants on how BQ can increase their risk for developing oral cancer. Findings from Sotto PP et al. (2020) revealed that BQ chewers underestimated the deleterious effects on health contributed by their chewing behaviour. A detailed explanation on this component will be covered in Methods Chapter.

The **behavioural component** in the intervention aims to replace chewing promoting behaviours to behaviours that are more conducive to staying quit. This involves identifying and managing triggers, making lifestyle changes that supports quitting and preparing for responses for social situation that might pressure participants to chew. Examples of lifestyle changes are such as reducing time spend or avoiding places where triggers to chew occurs and making BQ not readily available in house compounds. The participants will be equipped with trigger management and coping mechanism skills to increase their self efficacy to cease the habit. This component will largely be discussed in Methods Chapter.

The intervention will be conducted through a series of 5 support group sessions and an aid of a concise guide booklet. By undergoing this module, participants will gain more knowledge and awareness to change their their attitude and beliefs and will also be taught on improving their self-efficacy on managing social cues and other trigger factors that they face in their community. Thus, resulting them to be **more empowered to reduce or cease the risk habits**. Any participants that failed the intervention due to relapse will be motivated, assisted and recruited back into the intervention as quitting risk behaviour can be very challenging.

Fiore et al. (2000) claims a multi-component cessation program has achieved higher long term cessation rate of 25-30% and this study envisions that this soon-to-be adapted multi-component BQ cessation program will be instrumental for the behaviour change in the high risk communities in Malaysia.

3.0 MATERIALS AND METHOD

3.1 Overview of the Study design

This is a comparative prospective community trial which utilises a cluster randomised controlled trial design involving a Bajau indigenous community in Sabah, Malaysia with a 1:1 allocation ratio. The clusters are Bajau villages that practises BQ chewing habits in Kota Belud district in Sabah. The Bajau villages are the unit of randomisation. There are 39 Bajau villages in Kota Belud, Sabah (Tahir Z et al., 2003).

The clustered randomised controlled trial study design was selected as there was a high tendency of crossover if both intervention and control groups are randomised within the same village. Individuals allocated to a control group may inadvertently receive some aspects of the intervention if they are in proximity to the individuals in intervention group (Hahn S et al (2005). Thus, clustered randomised trial is the best available design for researchers who evaluating intervention that operates at group level, that manipulates the social and physical environment and cannot be delivered to individual participants without any substantial risk of contamination (NIH, 2022).

The eligible villages will be randomised into intervention and control groups based on the required sample size. The intervention group will receive an educational booklet and a structured BQ cessation program which will be cross- culturally adapted first based on a clinical trial (BENIT) by Paulino YC et al. (2020) for a Malaysian high risk population. The control group will only receive an educational booklet.

Baseline information on participant's demographics, BQ chewing behaviours, BQ composition, BQ dependency levels, reasons for chewing, the readiness and self perceived barriers to cease habit will be obtained prior to the commencement of the intervention. The

same participants will be followed-up at 22-day and 3-month after commencement of intervention to assess their of quitting experience and impact of the intervention. Day 22 follow-up was kept in this study as it will enable study results to be compared with similar BQ cessation studies in other parts of the world such as in Pacific Islansds (Moss J. et al., 2015 and Paulino YC et al., 2020).

3.2 Background of Study Location and Population

This study will take place in Kota Belud, Sabah. The state of Sabah has recorded the highest number of BQ chewers in Malaysia (2,283 people). BQ chewers contributed to 16.42% of the total individuals that practiced oral cancer risk habits in Sabah; based on the National Oral Cancer Screening report for the year of 2021, MOH (Table 3.1). Sabah is situated in East Malaysia, forming the northern part of the great island of Borneo. Although there is evidence of Chinese trade from the 7th century onward, Sabah's trade contacts were confined to the Philippines for centuries in the earlier days.

Table 3.1 Distribution of Oral Cancer Risk Habits in Malaysia in 2021
(Excerpted from National Oral Cancer Screening Report, MOH – Appendix 3)

No.	State & Federal Territory	Number with Oral Cancer Risk Habits	Number with BQ Risk Habits	Percentage with BQ Risk Habits (%)
1	**Sabah**	**13,893**	**2,282**	**16.42**
2	Selangor	6,990	200	2.86
3	Sarawak	1,624	136	8.37
4	Negeri Sembilan	3,222	166	5.15
5	Melaka	2,621	27	1.03
6	Johor	11,096	176	1.59
7	Perak	8,915	**420**	4.71

8	Kedah	7,676	211	2.75
9	Pulau Pinang	5,172	45	0.87
10	Perlis	1,622	9	0.55
11	Pahang	4,919	**461**	9.37
12	Kelantan	5,968	47	0.79
13	Terangganu	3,957	50	1.26
14	Kuala Lumpur & Putrajaya	4,936	33	0.67
15	Labuan	479	14	2.92

A further probe into the districts of Sabah revealed that Kota Belud (KB) had the highest number of people practicing the BQ chewing habit. Table 3.2 shows among 1,769 people with oral cancer risk habits in KB, 818 people practised BQ chewing habits (46.24%).

Table 3.2 Distribution of Betel Quid Users in State of Sabah, Malaysia in 2021
(Excerpted from National Oral Cancer Screening Report, MOH – Appendix 3)

No.	District Names	Number With Oral Cancer Risk Habits	Number With BQ Risk Habits	Percentage With BQ Risk Habits (%)
1	**Kota Belud**	**1,769**	**818**	**46.24**
2	Keningau	2,883	607	21.05
3	Kudat	2,038	369	18.11
4	Beaufort	1,102	232	21.05
5	Kota Kinabalu	2,311	132	5.71
6	Sandakan	1,863	97	5.21
7	Penampang	130	11	8.46
8	Tawau	1,330	8	0.60
9	Lahad Datu	467	8	1.71

Kota Belud is located at west coast of Sabah and was one of the first administrative district in Sabah during British occupation. It is located 70km from Kota Kinabalu, the capital of Sabah. The district has an area of 1,391 square kilometres and a population of 107,243 people (Department of Statistics, Malaysia, 2020). The three main ethnicities in Kota Belud are Bajau, Dusun dan Irranun. There is also a minority of Chinese in this district.

The gender distribution in this district is equal; 50.3% of males and 49.7% of females. Close to two-thirds of the population are between 15-64 years old (64.1%), followed by 30% who are between age 0-14 years old and a small percentage are above 65 years old (5.9%). Most of the population are Muslim, followed by Christianity and Buddhism and others.

The population of interest for this study in Kota Belud is the Bajau community. The Bajaus, are one of the indigenous groups in Sabah that still practises their traditional culture. They are often referred to as "cowboys of the east" as their lifestyle resembles the lifestyle of western cowboys. Their main language for communication is Malay, but the older generation are more familiar in their Bajau dialect. There are 134 villages in Kota Belud and 39 villages of it were dominated by Bajau people (Tahir Z et al., 2003).

3.3 Sample Population

The Bajau adults are considered as a high-risk individuals alongside Indians, Orang Asli and other indigenous communities in Sarawak and Sabah (OHD, 2018). A hisk-risk population is defined as communities that practices risk habits such as smoking, drinking alcohol and chewing BQ or living in a community which favours the tendency to take up those habits (OHD, 2002).

Table 3.3 shows that Bajau was the most dominant ethnic group that practiced BQ chewing habit in Kota Belud for the past two consecutive years compared to other races. Data was retrieved from Kota Belud's District Dental Office oral cancer screening report.

Table 3.3 Local District Screening Report of Ethnic Distribution of BQ Chewers in Kota Belud for 2021-2022

Ethnic	2021	2022
Bajau	**307**	**226**
Dusun	300	163
Bumiputera Sabah Lain	97	71

Tentatively, a total of 6 villages will be selected for the conduct of this study; 1 village for pre-test, 1 village for pilot test and another 4 villages for the implementation of the study (2 villages for intervention study and 2 villages for the control arm).

3.4 Sample Size

The sample size needed for this study will be calculated from a previous study performed by Herzog TA et al. (2022). The sample size was calculated using OpenEpi Version 3 software with the following assumptions:

- Margin of error (α error) : 0.05
- Power of study (1-β) : 0.8
- Allocation Ratio : 1
- Percent of Exposed with Outcome : 38.64 %
- Percent of Unexposed with Outcome : 9.09 %

A total of 76 participants are needed for this study and 38 participants in each arm. After calculation of 20% dropout at 22th day and in 3 months (16 people), a revised total of 92 participants are needed for this study with 46 participants in each arm (Figure 3.1)

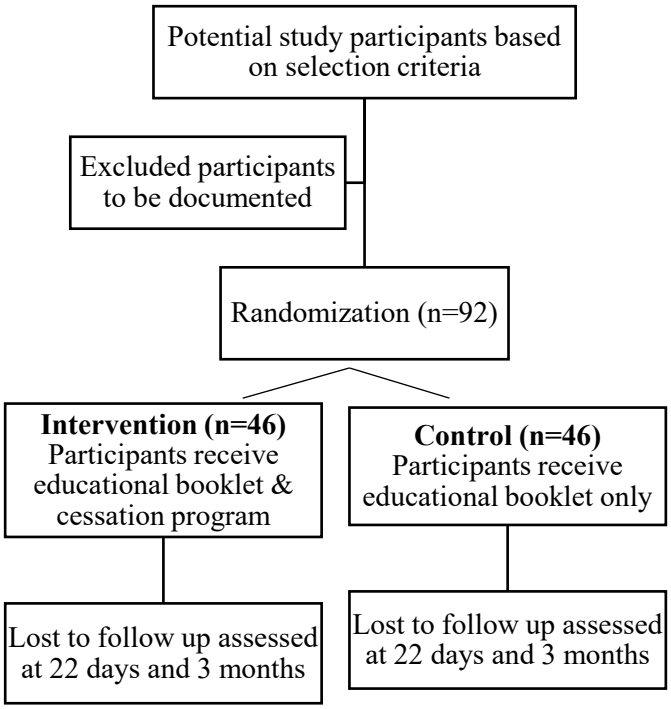


Figure 3.1 Flow of the Participant Allocation in the Study

3.5 Sampling and randomisation method

Prior to randomisation, matching of eligible Bajau villages will be carried out to increase precision and to minimise imbalance across intervention and control groups. This study involves 2 levels of randomisation. The randomisation sequence will be carried out by statistician employed at Faculty of Dentistry, Universiti Malaya.

At the first level of randomisation, all eligible Bajau villages from the total 39 Bajau villages will be paired according to location and average number of BQ chewers in the village (Figure 3.2).

At the second level of randomisation, computer generated random numbers will be used to randomly allocate the Bajau villages in each matched-pair to intervention and control groups. The match-pairs will be randomly selected until the sample size is met.

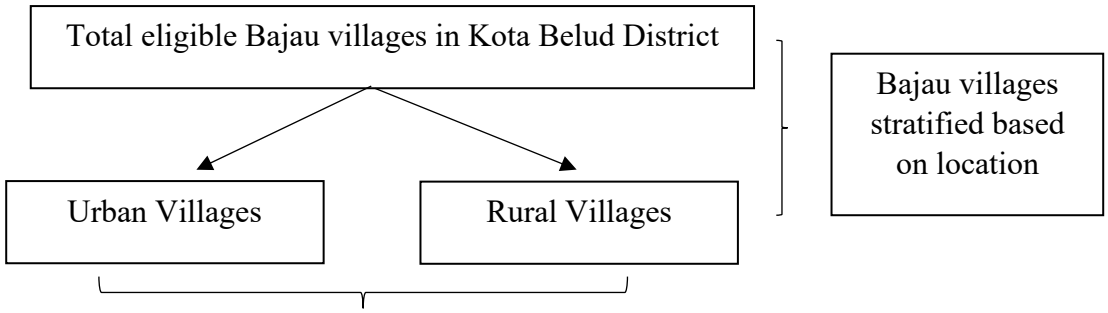


Figure 3.2 Diagram depicting Flow of Matching of Clusters in the Study

3.6 Allocation concealment

In this study, allocation concealment will be done at cluster level. A senior dental officer (SDO) in Kota Belud Dental District Office who is not involved in cluster identification and recruitment will keep the allocation sequence in a brown envelope in his or her SDO's office until the matched pair are ready to be recruited into the study.

The allocation sequence will be generated by a statistician employed at the Faculty of Dentistry, Universiti Malaya using computer generated tables. The information will be keep confidential until the intervention are assigned to the villages.

Within the cluster, a universal sampling technique will be used to recruit participants into the study. Universal sampling is also known as a total population sampling; which is a type of purposive sampling that involves examining the entire population that have a particular set of characteristics (Laerd Statistics, 2012). All eligible participants who fulfilled the inclusion and exclusion criteria through the screening session will be recruited as study sample. Thereafter, informed consent will be obtained from the participants.

3.7 Blinding

This study will utilise a single-blinding strategy in which only the researcher implementing the study knows which participant is receiving intervention until the trial is over. A single-blind study makes results of the study less likely to be biased. This means that the results are less likely to be affected by factors that are not related to the intervention being tested.

3.8 Selection criteria

The **inclusion criteria** for this study is as follows:

- A self-reported BQ chewer who has been chewing BQ for the past 6 months with atleast 2-3 chewing episode per week. The ingredient of BQ must include AN without or without smokeless tobacco.
- Other optional ingredients such as slaked lime and betel leaf are allowed.
- Age of participant must be 18 year old or above
- Participants must be residing in study location (Kota Belud, Sabah)
- Ability to comprehend, converse and read in Bahasa Melayu and their local language (Bajau)
- Participants who are able to provide written consent and agree to comply with all protocol-specified procedures such as providing saliva samples, participating in five 1-2 hours sessions of intervention over 22 days and agree to attend follow-up sessions on first and third month

The **exclusion criteria** for this study are as below:

- Non-Malaysian citizen
- Participants who are not willing to quit the BQ chewing habit at the time of the study
- Women who are pregnant or nursing at the time of study
- Individuals with psychiatric illness or special social situations that would limit their compliance with study requirements

3.9 Participant/Subject Withdrawal Criteria

The Main Researcher may withdraw (remove) a participant from some study components at her discretion if participant is non-compliant with required study regimens or procedures.

A participant can voluntarily withdraw from participation in some or all components of a study for which he or she has previously consented if he or she has a valid reason. Withdrawn participants will be replaced only if required sample size is not fulfilled.

3.10 Conduct of the Study

There will be 3 phases to the conduct of this study as below:

Phase 1 **Adaptation, Validation and Translation of the Questionnaire, Educational Booklet and Intervention Module**

Phase 2 **Pretest and Pilot test of the study**

Phase 3 **Implementation of the study (Field Work)**

The conduct of the study will be discussed in detailed manner according to the phases of the study.

3.10.1 Phase 1 Adaptation, Validation and Translation of the Questionnaire, Educational Booklet and Intervention Module

In Phase 1, there are 3 components that will undergo the adaptation; namely the baseline and follow-up questionnaire, educational booklet and intervention module. The details of these 3 components are described below in 6.10.1.1 till 6.10.1.3.

BENIT trial (Paulino YC et al., 2020) was selected as the intervention of choice to be cross-culturally adapted in Malaysia due to few reasons. Firstly, this is the first intervention of its kind that targets primarily the users of betel quid in an indegeous population that utilises areca nut. Other researches focusses more on smokeless tobacco. As Malaysian high risk community are more common to use areca nut singly and mostly without smokeless tobacco, thus BENIT was selected to be adapted in Malaysia for this study. There are other studies too from Pakistan that focusses on adolescents. Since the population that chews betel quid in Malaysia are above 40 years old, thus BENIT again was a more appropriate intervention to be adapated in Malaysian high risk community.

3.10.1.1 Baseline & Follow- up Questionnaire

A structured questionnaire (Appendix C) will be used in this study. The questionnaire will be adapted from the BENIT trial (Paulino YC et al., 2020). In the **baseline survey**, questions regarding demographics, BQ chewing behaviours, BQ composition, BQ dependency level, reasons for chewing, readiness and self-perceived barriers to quit will be asked.

On the 22-day, 1-month and 3-month, a follow-up questionnaire will be prepared. Information consisting of intervention compliance (whether they had attempted to quit chewing since start of the intervention), current chewing status (current chewer or ex-chewer), how much the participants had cut down on their chewing (quids/day), how many group sessions the participants attended (as well as reasons for absent if missed any sessions) and BQ composition if the participants are still chewing.

Several composites questions from other validated questionnaire will be added to existing questionnaire set to achieve a strategic fit to meet the objective of this study; BQ composition (Tahir Z & Doss JG, 2003), BQ dependency level (Herzog TA et al., 2014), reason for chewing (Little MA et al., 2014), readiness and self perceived barriers in ceasing the habit (Maling TH, 2016 & Brown RA, 2003).

Prior to formulation and adaptation of the questionnaire, permission to use and modify the established questionnaire will be obtained from original author (Paulino YC et al., 2020).

Below are the summaries,

The baseline questionnaire (Appendix C) will be comprised of:

a) Section A – to obtain demographics information of the study participants
b) Section B – to assess the BQ chewing behaviours (including chewing history)
c) Section C – to assess BQ composition used by the participants
d) Section D – to assess the BQ dependency level
e) Section E – to assess the reason for betel quid chewing
f) Section F – to assess the readiness and self perceived barriers to quit habit

The follow up questionnaire (Appendix M) (22-day, 1-month & 3-month) :

a) Section A – brief personal particulars of the participants
b) Section B – to assess participant's compliance towards the intervention by assessing the total number of session attended and reasons if absent
c) Section C – to assess the current chewing status
d) Section D – to assess number of cut-down of habits by the participants (quid/day)
e) Section E – to assess BQ composition (if still chewing)

3.10.1.2 Educational booklet

The educational booklet is a single booklet that will consist of a minimal intervention designed to encourage participants to quit BQ behaviour. This educational booklet will be adapted from the one used in the BENIT trial (Paulino YC et al., 2020) (Figure 3.3). The booklet will serve to provide general information regarding AN and BQ, risk associated with BQ chewing behaviour through captivating graphical aids, cessation strategies that are modeled after tobacco cessation and researcher's contact information to the participants. Both study groups will receive an educational booklet.

Cessation strategies will be designed in a heuristic manner. Heuristics are mental shortcuts that assist people to solve problems and make judgements quickly and efficiently (Marewski JN & Gigerenzer G, 2012). These strategies will shorten the decision-making time and allow participant to reduce risk habits without frequently stopping or procrastinating about their next reduction actions.

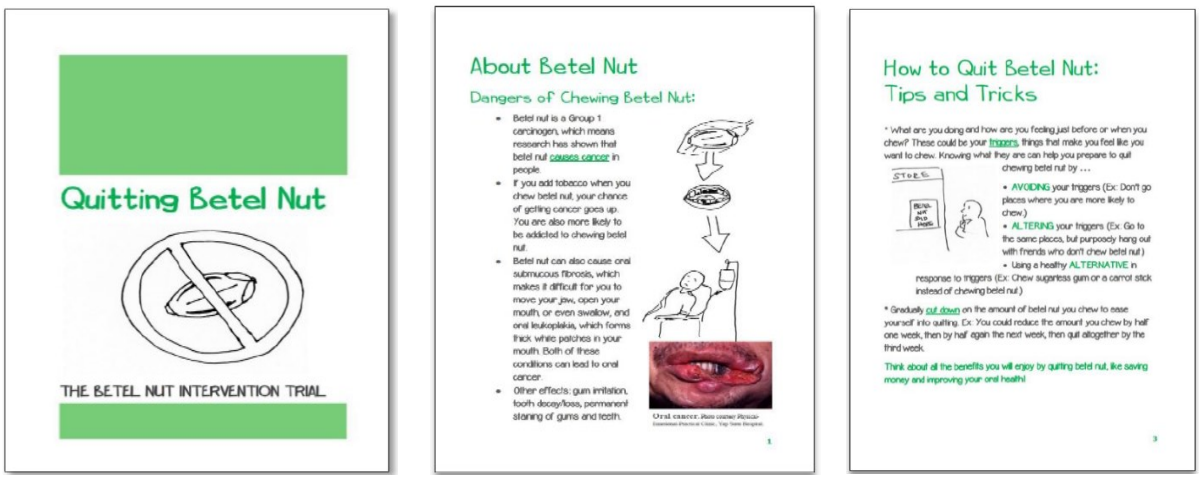


Figure 3.3 BENIT's Educational Booklet

3.10.1.3 Intervention module

The intervention module will be adapted from the one used in the BENIT trial (Paulino YC et al., 2020) and will consist of 7 worksheets as illustrated in Figure 3.4. This worksheet serves to guide participants to quit BQ chewing behaviour by increasing their understanding of the group session intervention and by increasing their self -efficacy in their quitting journey. All worksheets are explained in this section and are attached in the Appendix.

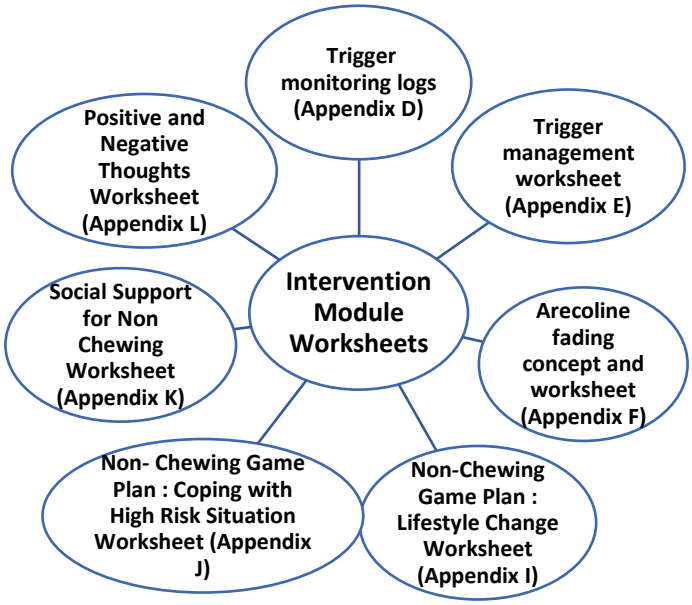


Figure 3.4 Summary of Intervention Module Worksheets

Trigger monitoring logs (Appendix D) are a personalised written records of the participant's triggers, the different types of triggers they experienced and the many varied situations that triggers them to chew. Common examples such as urge to chew after a meal or after meeting a close friend will be given to aid their comprehension and to obtain a more accurate data. The log will contain a record of the number of quids chewed in a day, the situation and mood that they were in prior they initated the chew. The record should be written before the participants start the chew.

Trigger management worksheet (Appendix E) is a worksheet of self control strategies that one can abide with to manage their trigger situation. In a single day, participants can experience many and varied types of triggers that lead them to chew. During the intervention, participants will only be encouraged to manage (intervene) in two or three triggers in a week. This is gradual approach is so that participants can cope with the withdrawal symptoms that results from these small changes. Participants will be guided on how to systematically decide on the subtle strategies to adopt. The worksheet will contain all strategies used and advocated by the participants. Chewers will be guided to tackle the easiest trigger situations first before moving to the more difficult situation. As chewers have a good sense of which situation they are more capable to intervene, they should be consulted first before the prescription of the trigger management strategies.

Arecoline fading concept and worksheet (Appendix F) is a worksheet that utilises the concept of gradually reducing the participant's physical dependence on AN. This worksheet will serve as a guide to perform the rate reduction method prior to the quit date. Participants will be advised to reduce 1 quid in a day for 2-3 days or at a rate of reduction of 10% consumption in 2-3 days. By adhering to this rate reduction method through a close monitoring from the worksheet, participants will be able to reduce the intensity of their

withdrawal symptoms on the quit day and this will make their quitting experience less difficult. This fading concept too could be a good substitute for pharmacological approaches.

Lifestyle Change worksheets will assist the participants to make lifestyle changes which are crucial for one to remain abstinent. There are 6 questions in the **Non-Chewing Game Plan : Lifestyle Change Worksheet (Appendix I).** The questions revolves around the lifestyle changes that the participants can make to assist them to quit the habit; namely "What will you do to make betel quid unavailable to you", "What will you do to increase time spent in non-chewing areas or doing non-chewing activities", "How can you get help from others while trying to quit", "What will you do to manage stress successfully", "What will you do from keeping from gaining weight" and "What will you do to be physically active".

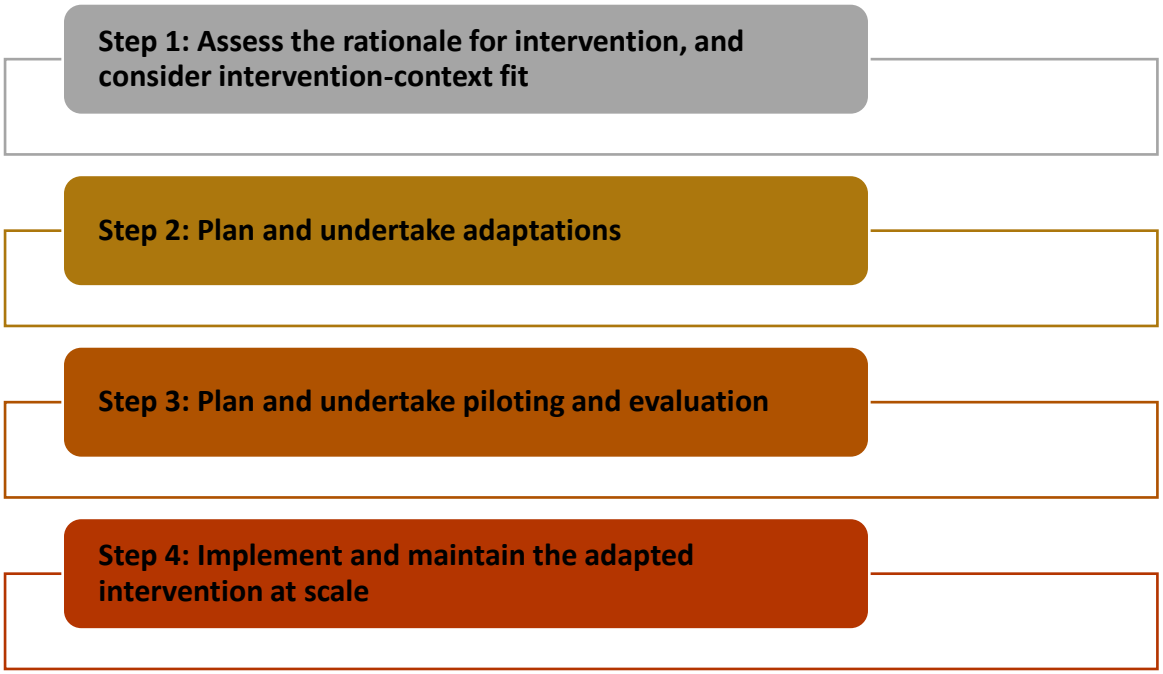
Non- Chewing Game Plan : Coping with High Risk Situation Worksheet (Appendix J) is another lifestyle change worksheet that are targeted to prepare participants for potential high risk situation that they may experience in their community and daily lives. For each specific high-risk situation that they participants can identify, description of the event, persons that they might be with, what were they doing, thinking, or feeling at the time will be asked to be recorded in the worksheet. Participant will be asked to develop and record a full set of coping strategies to deal with their situation so that they could remain not chewing in such environment. They are required to utilise the 3As (Avoid, Alter, use Alternatives) of coping mechanism skills and document it in this worksheet. This worksheet really aids in their efforts to replace chewing behaviour to an abstinent one.

Social Support for Non Chewing Worksheet (Appendix K) is a tool to maximise the social support of the participant to quit the behaviour. Social support can be a good source

of motivation and may also act as a buffer for stressful situations. Thus, they are required to identify and record behaviours of others that are helpful and not helpful in their non-chewing efforts, and also activities that the participants would like others to increase or decrease to help participants in the their journey of quitting chewing.

Positive and Negative Thoughts Worksheet (Appendix L). In this worksheet, the participants will be asked to keep track of their positive and negative thoughts throughout the intervention. Thoughts which contain clear message of positivity or negativity should be recorded. Later, participants will be asked to record a self technique to increase their positive thoughts and a self technique to reduce their negative thoughts and how effective it was for them.

The questionnaire, educational booklet and intervention module will undergo adaptation process through ADAPT framework (Moore G et al. 2021) as below:

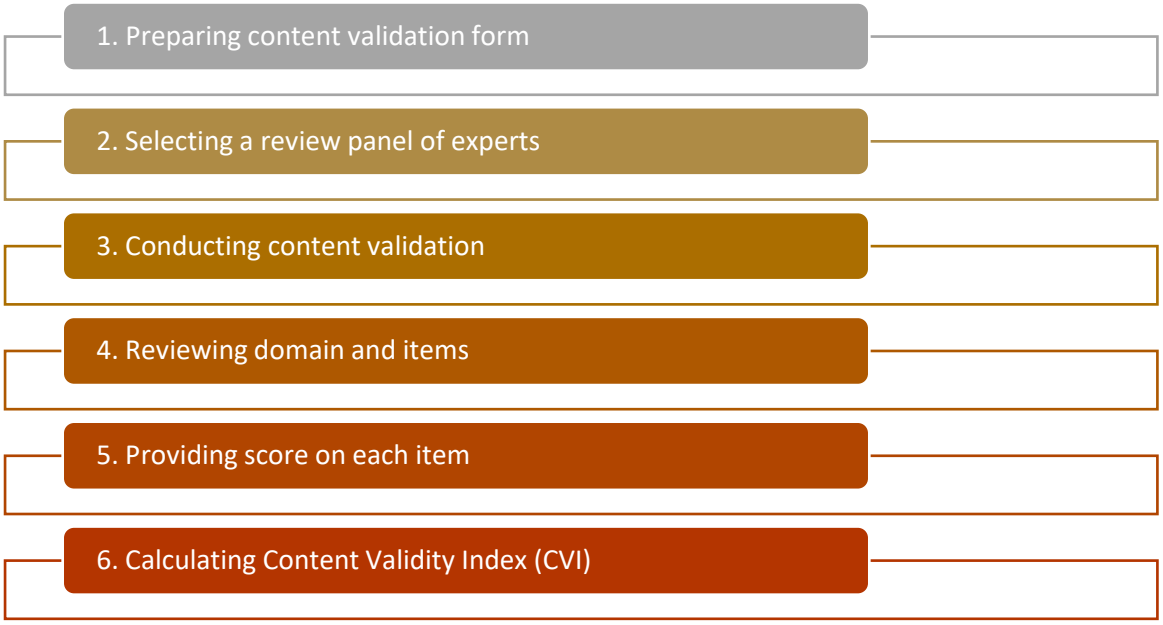


3.10.1.4 Questionnaire, Educational Booklet and Intervention Module Validation

The questionnaire, educational booklet and intervention module will be set in English and face validation will be undertaken by researchers. Later it will be submitted to smoking cessation experts from Department of Social and Preventive Medicine and Centre of Addiction Science, Universiti Malaya for content validation.

The experts will be required to review questionnaire, educational booklet and intervention module items for clarity and appropriateness based on the study's intended objectives. A further necessary modification will be undertaken after obtaining the comments and suggestions.

In summary, the content validation procedure will include 6 steps (Yusoff MSB, 2019) as below:



3.10.1.5 Questionnaire, Educational Booklet and Intervention Module Translation

The validated questionnaire, educational booklet and intervention module will later undergo an independent forward-backward translation. Firstly, the validated material (source) will be independently translated using a forward translation technique to the target language '*Bahasa Melayu'* (the national language) by two bilingual linguistic experts. The linguistics will later meet to review their translation together to search for inconsistencies with the original English set. Any difference of opinion will be resolved via reconciliation process, to come out with a single provisional forward translation.

The translated questionnaire, educational booklet and intervention module will then be independently back-translated to English by another two bilingual linguistics. They will compare the back translation and the original form of questionnaire for semantic equivalence. Semantic equivalence is a declaration that two data elements from different vocabularies contain data that has a similar meaning. This will ensure that the provisional forward translation is adequate representation of the original English set.

3.10.2 Phase 2 Pre-Test and Pilot Test

3.10.2.1 Pre-Test

The forward translation will then be pretested among 8-10 participants from a Bajau community in Kota Belud, Sabah, which will not be selected as the sample of the field study. This cognitive debriefing (pretest) will help to assure the clarity and non-ambiguity of the questionnaire to both the interviewer and subject. This will later allow for cross- cultural adaptation of the questionnaire in terms of conceptual and operational equivalence. Pretesting helps in ensuring that questionnaire is valid and could smoothly be administered to the

participants. A face-to-face interview will be carried out by the main researcher and the duration of each interview will be kept to below 30 minutes.

3.10.2.2 Pilot Test

Once modification from the pretest findings have been done, a subsequent pilot test will be done on the questionnaire, educational booklet and intervention module to assess its feasibility and psychometric properties. The pilot test will include close to 20-30 participants; again those who will not be selected as samples of this study or samples from the pretest. Later, the internal consistency of the items will be assessed to determine its reliability.

A focus group discussion will be utilised to garner patient's feedback of the intervention program. Questions such as language use, length of intervention and duration of each session, clarity and usefulness of the worksheet in creating awareness and suggestion for improvement will be obtained from participants.

Prior to the conduct of the pilot test, the participants will be briefed regarding the purpose of the study and will be provided with a 'Patient Information Sheet (PIS)' (Appendix A) that will contain the study information. A written consent too (Appendix B) will be obtained from the participants prior to the pilot test.

3.10.2.3 Training of Intervention Facilitators

A two days training will be conducted by the main researcher. Seven to eight staff who are identified by the Senior District Officer will be involved as questionnaire and worksheet interviewers and verbal translators for this study. Dental officers, dental therapists and dental assistants will be the staff of choice to be the facilitators in this study. They are required to be conversant in Bajau language; especially to support the older section of the participants who are more familiar in their local dialect.

The task of the staff is to explain the questionnaire and worksheets items and to be able to assist participants to complete them as accurately as possible. During the talk sessions, the staffs will act as verbal translators and also assist in the question and answer sessions. The delivery of cessation intervention will mainly be in Malay language delivered by the main researcher. The staff will also assist to collect and verify the responses given by participants in the homework logs such as trigger monitoring logs, trigger management, the non chewing game plan worksheets, social support and thought management worksheets.

During the training, the staff will be introduced to the intervention program; the aims and objectives to achieve, the number and brief explanation about the support sessions and the other method of evaluation at the end of the program. A simulation session will be planned to practically expose the staff to the order and details of this intervention. Staff who are not involved in this study will be recruited to act as a BQ chewers to train the staff who are selected to be the facilitators. The names of all the facilitators will be presented and registered under the National Medical Research Registry (NMRR), Ministry of Health (MOH), Malaysia.

Through the simulation, the main researcher could gain some insight on the possible shortcomings or issues that may arise during implementation. Appropriate remedial action and modification can done before intervention commences. A training manual will be prepared for each staff.

3.10.3 Phase 3 Implementation of the study (Field Work)

3.10.3.1 Initiatives to promote study

Prior to the start of the intervention, a **promotional initiative** will be conducted with the village head 3 weeks before the implementation of the study. The purpose of this promotion is to provide knowledge and convince the village head regarding the ill effects of the chewing habit. By agreeing and cooperating to this intervention, his villagers will receive the very first kind of such an intervention in Malaysia to curb the villager's 'addiction'. With adequate knowledge and a right attitude, the village head can have a positive predisposition to encourage his villagers to participate in this beneficial program. Once the trust of the 'strongman (the village head) has been gained', it will be easier to conduct the multi-component intervention in those villages.

Attractive posters and flyers will be distributed to the village head to paste in the allowed public places and for door-to-door flyer dissemination to ensure the villagers are aware of the intervention on the said date. The intervention will be carried on a weekend to obtain maximum participation.

One week before the implementation of the study, villages will be reminded of the program date and villagers who practises BQ habits will be advised to attend the intervention together with family members, relatives or neighbours who also has the similar habit. Moss J et al. (2015) claimed intervening the surrounding community with the similar risk habits can ensure the long term sustainability of habit cessation among chewers.

The first day of the program will be the screening day.

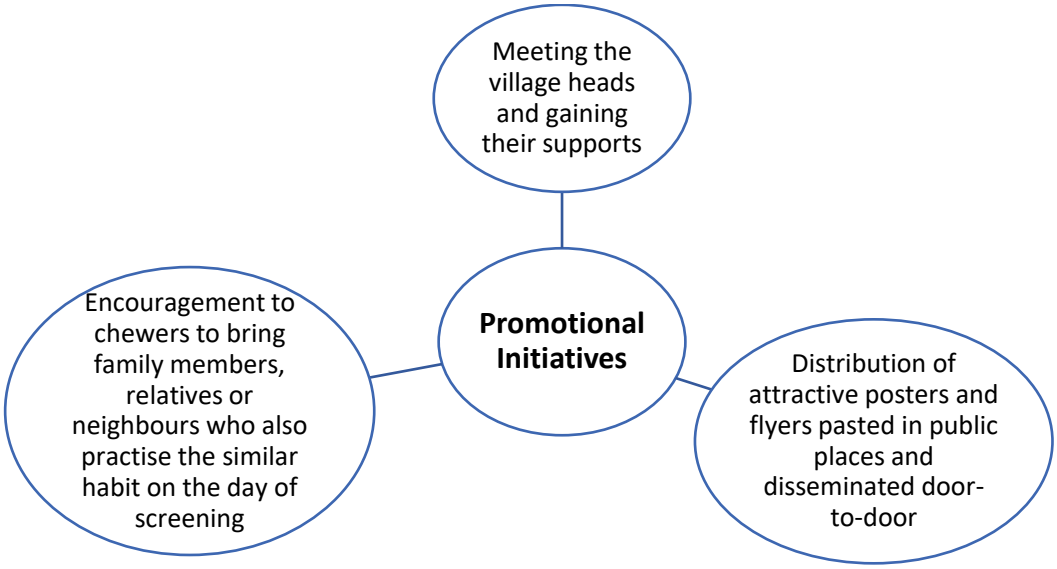
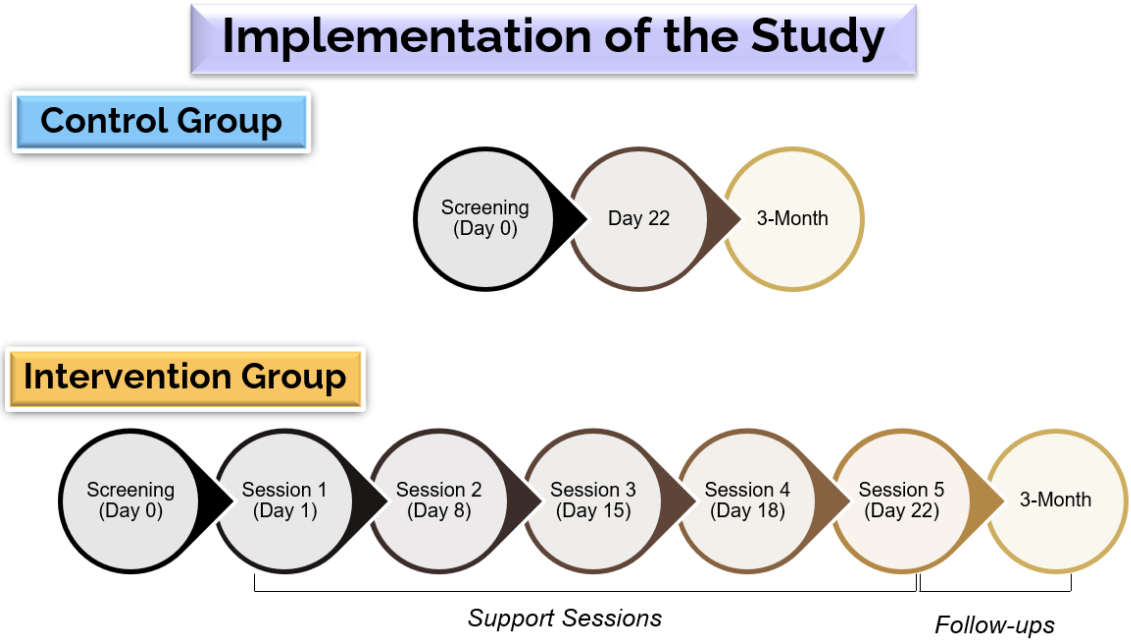


Figure 3.5 Summary of Promotional Initiatives

3.10.3.2 Implementation of the Study



Control Group

The community screening program for the control group will be organised at the community hall. Villagers who attended the screening program will first be registered and screened for eligibility to participate in the study (**Checkpoint 1**). The eligible participants will be briefed on the nature of the intervention and will be invited to participate. A copy of 'Patient Information Sheet' (PIS) (Appendix A) will be explained and given for reference about the study details and written informed consents (Appendix B) will be obtained from the villagers prior admitting them into the study.

Only consented participants will be interviewed by the trained interviewers (**Checkpoint 2**). Information regarding demographics details and baseline information of BQ chewing behaviours, BQ composition, BQ dependency levels, reasons for chewing, readiness and self-perceived barriers to quit will be obtained. No intra-oral clinical examination will be carried out in this study.

Upon completing of the interview, participants will be given an educational booklet which contains general information regarding AN and BQ, risk associated with BQ chewing behaviour, cessation strategies that are modeled after tobacco cessation and researcher's contact information. After an one-to one explanation about the educational booklet to the participants by the interviewer, they will be ushered to saliva collection counter (**Checkpoint 3**) to provide their baseline saliva sample. Participants will be thanked and given a token of appreciation before they are ushered out of the community hall.

Participants will be provided with an appointment card to return on the 22-day, 1-month and 3-month for follow-up. Follow-up questionnaire and saliva samples will be taken on 22-day and 3-month, whereas a community perception analysis will be performed at 1-

month together with completion of follow-up questionnaire. The summary of participant's flow for the control group is illustrated in Figure 3.6.

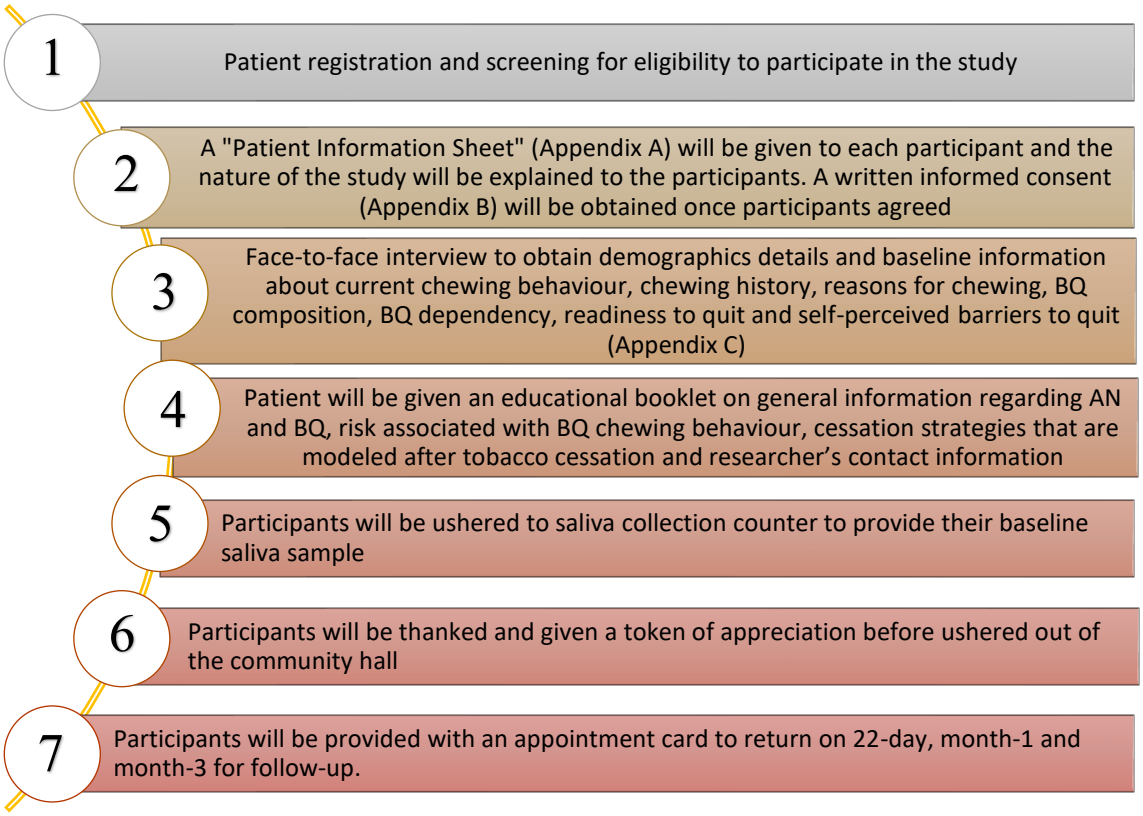


Figure 3.6 Summary of Participant's Flow for the Control Group in this study

Intervention group

<u>Screening (Day 0)</u>

The community screening program for the intervention group will be organised at the community hall on a Saturday. Villagers who attend the screening program will first be registered and screened for eligibility to participate in the study (**Checkpoint 1**). The eligible participants will be briefed on the nature of the intervention and will be invited to participate. A copy of 'Patient Information Sheet' (PIS) (Appendix A) will be given for the reference about the study details and written informed consents (Appendix B) will be obtained from the villagers prior admitting them into the study.

Only consented participants will be interviewed by the trained interviewers (**Checkpoint 2**). Face-to-face interviews will be carried out to gain participant's information regarding demographics details and baseline information of BQ chewing behaviours, BQ composition, BQ dependency levels, reasons for chewing, readiness and self-perceived barriers to quit habit. No intra-oral clinical examination will be carried out in this study.

Upon completion of the interview, participants will be briefly explained and given an educational booklet which contains general information regarding AN and BQ, risk associated with BQ chewing behaviour, cessation strategies that are modeled after tobacco cessation and researcher's contact information. They will then be ushered to saliva collection counter (**Checkpoint 3**) to provide their baseline saliva sample.

Participants will be thanked and given a token of appreciation before being ushered out of the community hall and will be reminded to return the next day (Sunday) to initiate the first support session for the cessation intervention. For every intervention session attended by the participants, they will be monetarily incentivized for their time and commitment for cessation. Appointment card will be provided to ease participants reference of support session dates.

A self explanatory video presentation regarding general information of AN and BQ, the ill health effects of BQ and introduction and importance of cessation program will be continously played **for the non- chewers in the village hall** to increase their knowlege and awareness while they are waiting for their family members. who are undergoing the screening. This can help maximise their support for their loved ones who are trying to quit the risk habit.

The subjects will be assigned into a group of seven participants and the appointments for each group participants will be given across the week. A total of 2 group sessions will be made in a day; a morning session and an afternoon session. Participants will be sought of their preferred time to increase participation in the intervention group.

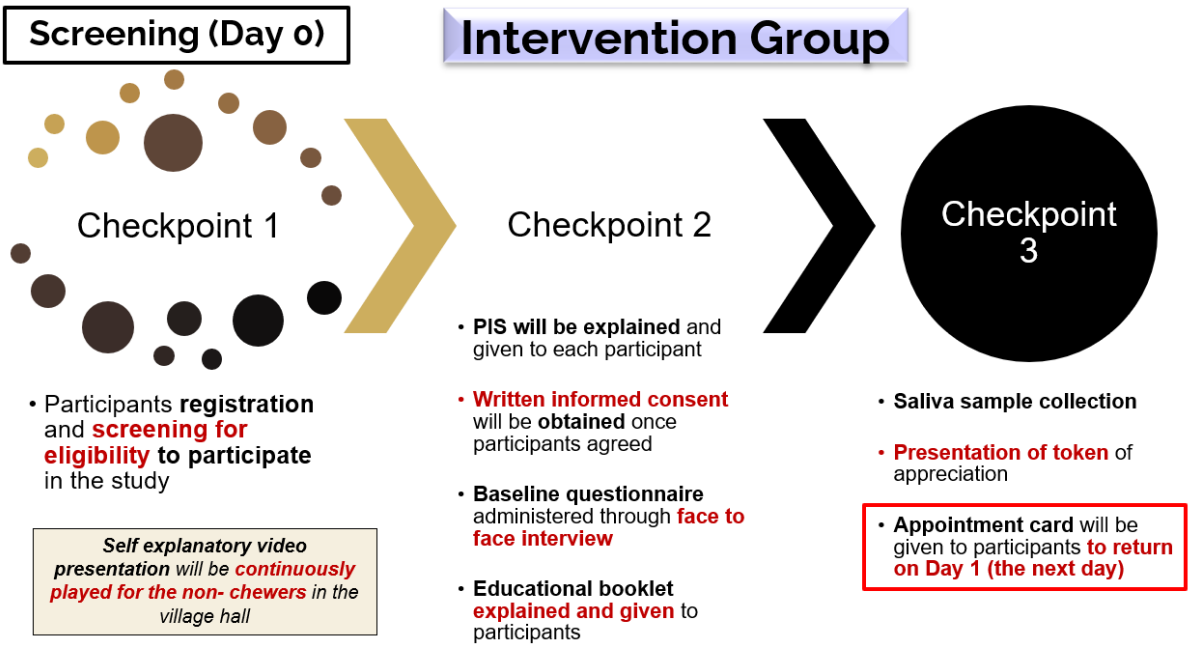


Figure 3.7 Flow of Participants on the Screening of the study (Day 0)

1st Session (Day 1)

On the **1st session of the intervention (Day 1),** attendance of all eligible and consented participants will be be taken at **Checkpoint 1** and the nature of intervention will be introduced through a **brief talk**. The information that the participants will undergo 5 sessions of support and information group designed to assist them to quit BQ chewing habit over 22 days period will be emphasized and they will be reminded that their continuous commitment to the intervention is utmost important to their future cessation.

They will also be briefed that each support session will consume approximately 1-2 hours. It will be conducted by the main researcher in Malay language (Bahasa Melayu) and

translated by trained facilitators into Bajau language verbally. A translation script will be prepared before initiation of the intervention for standardization to minimise bias or any poor explanation in Bajau language.

After the brief introduction, an **educational talk** will be delivered to the study participants by the main researcher. The content of the talk will be based on the topics of the educational booklets (general information regarding AN and BQ, risk associated with BQ chewing behaviour through projection of captivating graphical aids, cessation strategies that are modeled after tobacco cessation and researcher's contact information) but in a more detailed and interactive manner. An aid of Microsoft Powerpoint multimedia presentation will be used. A two-way communication mode will try to be sought throughout the entire talk. Participants will be encouraged to participate actively during the educational talk session. The aim of the educational talk is to increase the chewer's awareness, motivation and to enhance their commitment to cease behaviour. Participants too will be encouraged to share their experience and their feelings of chewing BQ and what are the challenges they face while practicing this habit.

Following the talk, participants will be introduced on the **topical worksheets**. For Session 1, 3 topical worksheets will be administered to participants; trigger monitoring logs (Appendix D), trigger management logs (Appendix E) and arecoline fading worksheet (Appendix F). A brief explanation regarding triggers to chew BQ, example on how and different types of strategies available which could be utilised to manage the triggers and the concept of arecoline fading will be discussed with the participants. Three checkpoints will be prepared to assist participants practically and individually on how to fill the worksheet. Before proceeding to the checkpoints, participants will be divided into a group of 7 people and will be assisted by trained facilitators on completion of the worksheets.

Checkpoint 2 will cater for the completion practice of trigger monitoring logs (Appendix D). Explanation regarding what are triggers, different types of triggers and situations that make this triggers arise to promote chewing behaviours will be further discussed individually based on participant's experience. Common examples such as urges to chew after a meal or after meeting a close friend will be explained to participants to aid their comprehension. Participants will be asked to keep a written record of the number of quids chewed in a day, the situation and the mood that they are in prior to the initation of the chew. The record should be written before the participants start the chew. The daily records of trigger logs of a minimum of 3-4 days will be required for a good analysis.

Checkpoint 3 will cater for the completion practice of trigger management log (Appendix E). This management strategies are self-control strategies that one can abide with to manage their trigger situation. In a single day, participants can experience many and varied types of triggers that lead them to chew. During the intervention, participants will only be encouraged to intervene in two or three triggers in a week. This gradual approach is so that participants can cope with the witdrawal symptoms that results from the small changes. Participants will be guided on how to systematically decide on the strategies. All strategies used and advocated by the participants should be written in the worksheet. It is best that chewers tackle the easiest trigger situations before moving to a more difficult situation. Chewers would be first consulted in this management strategies as they are the best persons who have a good sense of their situations and which that could be intervened.

Checkpoint 4 will cater for the completion practice of arecoline fading concept and worksheet (Appendix F). The rationale of this concept is to gradually reduce the participant's physical dependence on AN. This can be done through the rate reduction

method prior to the quit date. Participants will be advised to reduce 1 quid within 2-3 days or at a reduction rate of 10% BQ consumption in 2-3 days. By applying this concept, participants will be able to reduce the intensity of their withdrawal symptoms on the quit day and make their quitting experience less difficult. This fading concept can be a substitute for pharmacological approaches and can be eliminated for participants who would like to quit in a cold turkey manner on the quit date.

From **Checkpoint 2-4**, participants will be required to fill their triggers and strategies that they personally could make to manage their triggers. Participants will be given a firsthand experience on it by the facilitators guiding the participants to remember the previous day's triggers and ways they could manage those triggers. With personalised examples and guidance, they will be more self-efficient to complete worksheets in the following days. Participants will be required to fill those worksheets for a minimum of 3-4 days. The **worksheets will be collected by facilitators on Day 5 (Friday)** of the following week. The main researcher will review the trigger logs and trigger management logs to provide a summary on Session 2.

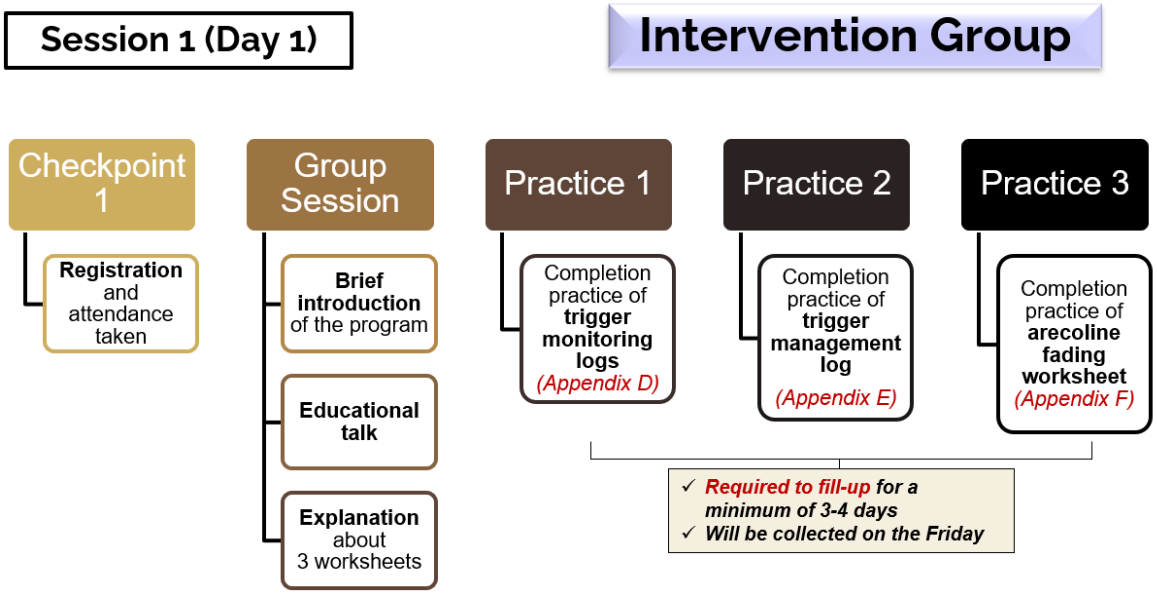


Figure 3.8 Summary of Participant's Flow on the 1st Session of the Intervention (Day 1)

2nd Session (Day 8)

On the **2nd session of the intervention (Day 8**), after participants are registered at Checkpoint 1, **a summary talk of the triggers within that community (village) and potential strategies to manage** triggers given by the participants will be projected and further discussed. Participants will be briefed that quitting chewing is more than cutting down the betel quid numbers or antagonising the triggers. A lifestyle change is very pertinent in making an ex-chewer remain abstinent. Strategies such as lifestyle changes, excuses to reject chew invites and usage of fake chew objects will be taught to participants to empower them to manage their triggers.

Checkpoint 2 will be prepared for completion practice of Lifestyle Change : Non-chewing Game Plan Worksheet (Appendix I). There are 6 questions in this worksheet regarding the lifestyle changes that the participants can answer to assist them to quit the habit; namely "What will you do to make betel quid unavailable to you", "What will you do to increase time spent in non-chewing areas or to increase doing non-chewing activities", "How can you get help from others while trying to quit", "What will you do to manage stress successfully", "What will you do from keeping from gaining weight" and "What will you do to be physically active (if it is relevant)". All these 6 questions will be explained further to participants by the facilitators followed by discussion with the participants.

Checkpoint 3 will be prepared for completion practice of Coping with High Risk Situation : Non-chewing Game Plan Worksheet (Appendix J). For each specific high-risk situation identified, participants will be ask to describe the event, persons that they might be with, what were they doing, thinking, or feeling at the time. Participant will be asked to develop a full set of coping strategies to deal with the situation without chewing. They will

be reminded that these high risk situations are temporary. They can utilise the 3As (Avoid, Alter, use Alternatives) of coping mechanism skills (Appendix H) and relaxation exercises (Appendix G). The participants will be reminded that this is a crucial planning for them to remain abstinent.

Checkpoint 4 will be prepared to teach participants on the **brief relaxation strategies** (Appendix G). Meditative and deep-breathing technique are taught to participants. Participants will be reminded that daily use of this relaxation procedure can help reduce chewer's overall stress level; which in return may help participants to quit chewing more easily. The participants can utilise this strategy to avoid the urges to chew and to manage their triggers. These strategies will take around 10-20 minutes and can be performed while sitting on a chair.

Checkpoint 5 will be prepared to teach participants on the **brief coping skills** (Appendix H). Without being equipped with skills to cope for stressful environment, it will be impossible of any chewer to be a permanent non-chewer. Bandura (1997) stated successful coping with high risk situation leads to increase sense of self-efficacy and determines an individual's probability of maintaining chewing abstinence. Three main coping skills will be taught to participants (3As); avoiding the trigger, altering the trigger situation and finding an alternative when the chewing trigger arise.

All checkpoints will serve to practically guide participants on their checkpoint topics. At the end of Session 2, participants will be reminded of the quit day that will be on Day 15 (the morning of the third session) and concept of arecoline fading too will be re-emphasized.

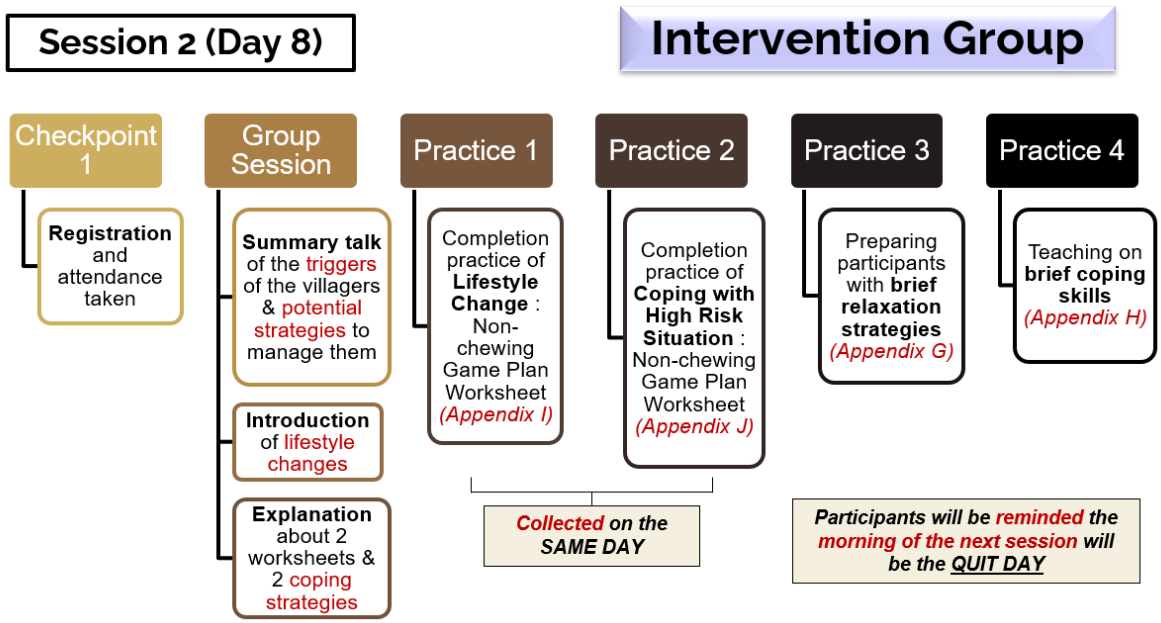


Figure 3.9 Summary of Participants' Flow on the 2nd Session of the Intervention (Day 8)

3rd Session (Day 15)

On the **3rd session of the intervention (Day 15),** it will be the quit date for the participants. Participants will be registered at **Checkpoint 1**. Main researcher and facilitators will discuss with the participants about the potential withdrawal symptoms that they may experience. Participants will be made aware that withdrawal symptoms will only persist at most up to 2 weeks, and after that period, the symptoms will fade away and not cause any difficulty. Coping strategies to combat the withdrawal symptoms will be discussed with the participants to help prevent any relapse **(Checkpoint 2).** The main researcher and facilitators will remain supportive to the participants and not to act in a judgmental manner regardless of the individual's chewing status. Physical activities that are suitable for elderly and within the vicinity of the community will be recommended for participants to cope with the withdrawal symptoms.

Checkpoint 3 will be prepared for completion practice of Social Support for Non-BQ Chewing Worksheet (Appendix K). It is a tool to maximise the social support of the participant to quit the behaviour. Social support can be a good source of motivation and may also act as a buffer for stressful situations. Thus, they play a positive role in the success of participants in remaining abstinent. Thus, in this checkpoint, the participants will be guided to identify their social support and record behaviours of others that are helpful and not helpful in their non-chewing efforts, and also activities that the participants would like others to increase or decrease to help them in the their journey of quitting chewing. Facilitators will personally guide the participants to complete this worksheet to give them a headstart.

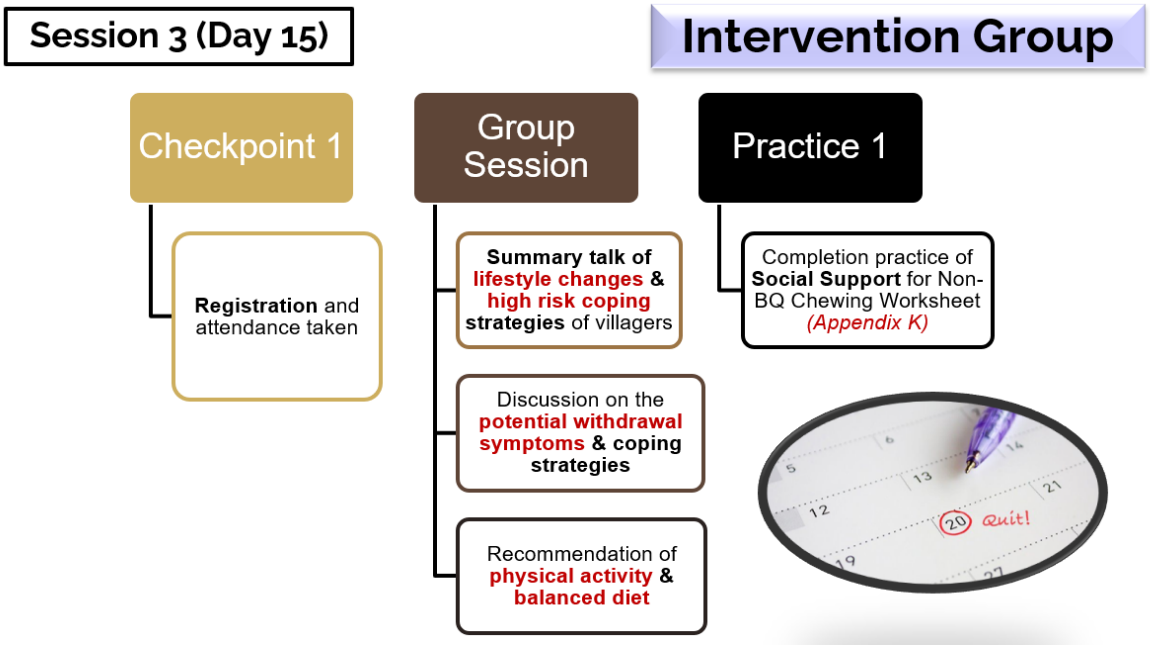


Figure 3.10 Summary of Participants' Flow on the 3rd Session of the Intervention (Day 15)

4th Session (Day 18)

On the **4th session of the intervention (Day 18)**, participants will be registered at Checkpoint 1. Discussion on the overall quitting experience of the participants will be held in the hall on how participants coped with triggers, the challenges in the high risk situations and the benefits they gained from the 3 days of quitting experience will be the highlighted during the discussion. The arecoline fading worksheet will be collected and reviewed and discussed with participants. The facilitators will further emphasize the negative health effects of BQ chewing and accentuate the oral cancer risk that is contributed by BQ chewing behaviour. Additional coping strategies will be discussed to address newer urges to chew. Reinforcement will be given for both quitters and current chewers through a talk by the main researcher.

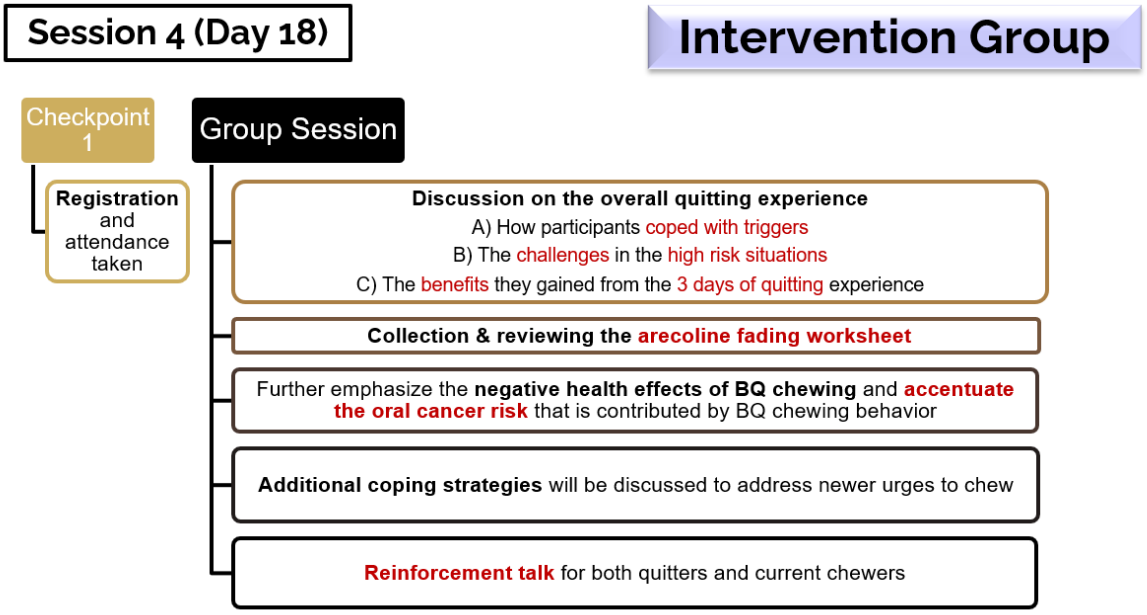


Figure 3.11 Summary of Participants' Flow on the 4th Session of the Intervention (Day 18)

5th Session (Day 22)

On the **5th session of the intervention** (**Day 22)**, participants will register their attendance at **Checkpoint 1** and will be required to complete a follow-up questionnaire. The questionnaire will enquire regarding brief personal particulars, patient's compliance, current chewing status, number of cut-down of habit by the participants (quid/day), total number of sessions attended and reasons if absent and the BQ composition if participants are still chewing.

Later, a discussion on the overall quitting experience will ensue**.** Participants who have relapsed and started chewing but are willing to attempt to quit again will be encouraged. **Strategies for managing thoughts** that could lead to relapse will be introduced. The participant's lifestyle changes that supports quitting will be reviewed. Usage of "excuses" for not chewing and employing "fake chew**"** will be reinforced.

The **Positive and Negative Thoughts Worksheet (Appendix L)** will be a strategy to manage the thoughts that participants might have through their quitting journey. This method is based on the notion that mood is related to the balance of the positive and negative thoughts. When negative thoughts outweighed the positive thoughts, the result is a depressive, anxious, angry or other symptoms that precipitate the behaviour of risk habit such as chewing to overcome it (Brown RA et al. 2003). The thoughts with a clear message of positivity or negativity should be recorded and it is curcial to discern which type of thoughts dominates in this process. The negative thoughts can be managed with the coping skills that they were thought before. The main researcher will brief all participants regarding this thought management through a talk.

Checkpoint 2 will be prepared for completion practice for Positive and Negative Thoughts worksheet (Appendix L). One of their current positive and negative thoughts will be used as a practice. At the end of session 5, **Checkpoint 3** will be prepared as saliva collection counter for participants to provide their 22-day saliva samples.

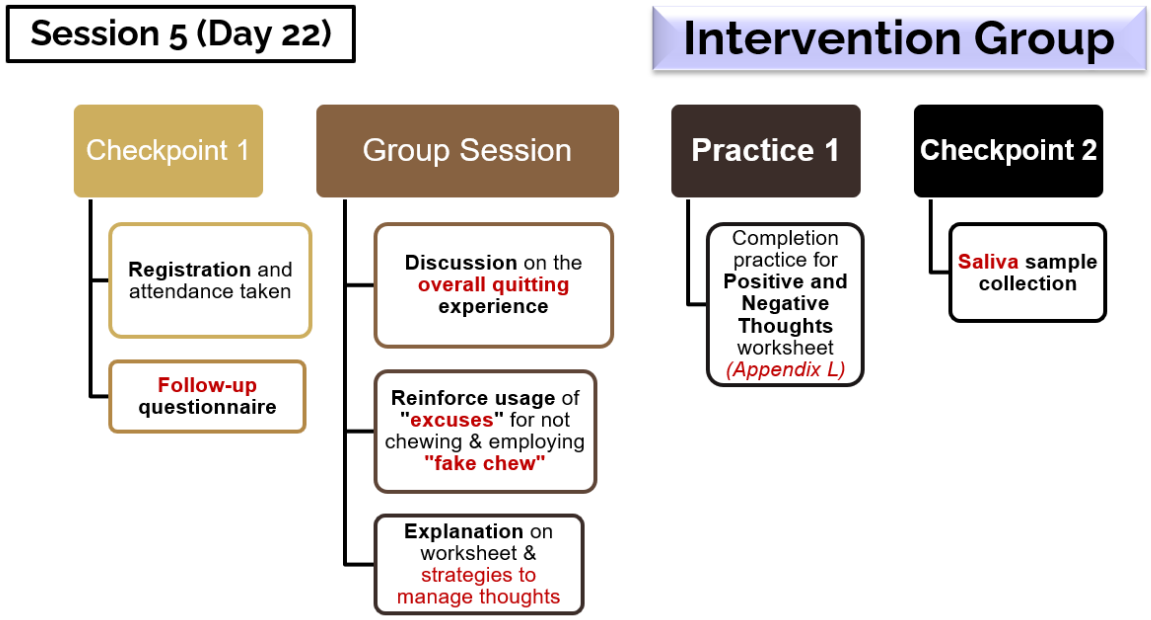


Figure 3.12 Summary of Participants' Flow on the 5th Session of the Intervention (Day 22)

3-month follow up (Day 90)

On **3- Month follow up**, participants will be assessed of their chewing abstinence through a follow up questionnaire after registration (**Checkpoint 1**). The items that will be required are brief personal particulars, participant's current chewing status, number of cut-down of habit by the participants (quid/day) and BQ composition if participants are still chewing. All participants will be motivated and encouraged regardless their success in quitting the BQ behaviour. A repeated educational talk of adverse effects of AN and BQ chewing habit will be given. A summary of community perception will be informed to the participants and they will be encouraged to contact research team if they needed any form of help in cessation in the future.

Checkpoint 2 will be prepared as a saliva collection counter for participants to provide their 3-month saliva samples. Participation on each session of the intervention and follow-up will be monetarily incentivized to maximise the participation rate.

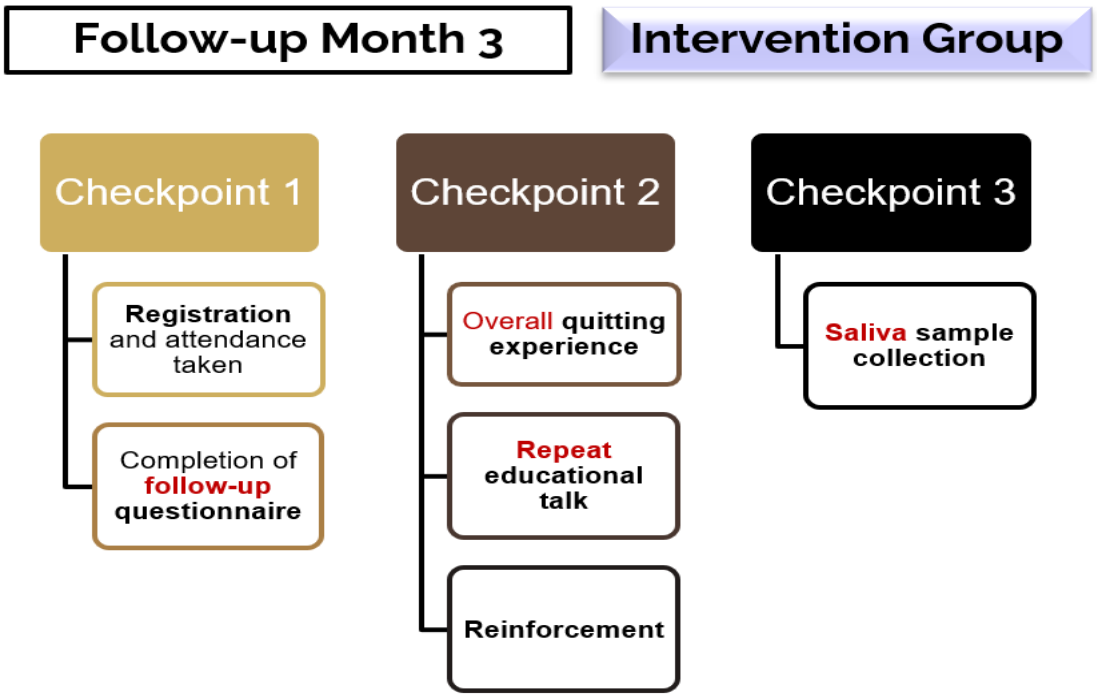


Table 3.13 Summary of Participants' Flow on the 3-Month Follow up of the Intervention (Day 90)

Table 3.4 Descriptive Summary of Intervention Arm Activities

Session	Day	Description of Session By: Brown (2003), Moss et al (2015)	Document Reference
1	1	**Introduction of program, ground rules, informed consent**	
		• Health effects of AN and BQ chewing, esp. oral cancer risk	
		• Discussion on self - monitoring for triggers (logs introduced)	**Appendix D**
		• Discussion on trigger management log (logs introduced)	**Appendix E**
		• Discussion on concept of arecoline fading and rate reduction prior to quitting (log introduced)	**Appendix F**
2	8	**Review trigger logs, discuss self - management approach**	
		• Discussion on lifestyle change to support quitting (logs introduced)	**Appendix I & J**
		• Discussion on "excuses" for not chewing, usage of "fake chew"	
		• Explanation about brief relaxation exercise and coping skills	**Appendix G & H**
		• **Reminder** to participants about arecoline fading and that Quit Day is morning of the next session	
3	15	**QUIT DAY.** Facilitator is tasked with reminding participants to be supportive and non-judgmental, regardless of individual chewing status	
		• Remind participants that withdrawal symptoms, if applicable, are generally worse in first 2 weeks, but will pass	
		• Discuss coping strategies to prevent relapse	
		• Plan to maximize social support for non – chewing (eg. talk) (log introduced)	**Appendix K**
		• Recommend physical activity (if applicable)	
4	18	**Overall discussion of quitting experiences**, including coping with triggers and high - risk situations, short - term benefits from quitting chewing	
		• Discussion on negative health effects of AN/BQ chewing again, including oral cancer risk (reinforcing this throughout derived from pilot testing)	
		• Discuss additional strategies for coping with urges to chew	
5	22	**Continue overall discussion of quitting experience**	**Follow -up Questionnaire**
		• Encourage participants who have relapsed to attempt to quit again	
		• Introduce strategies for managing thoughts that can lead to relapse	**Appendix L**
		• Review lifestyle changes that support quitting	
		• Reinforce usage of "excuses" for not chewing, employing "fake chew"	
		• Final remarks about planning for the future	

3.11 Saliva Test Protocol

3.11.1 Saliva Collection

The saliva collection tool should be about 20 mL in length and in a conical shape polypropylene tubes. An amount of 1 – 2 mL saliva sample will be collected during assessment by the Main Researcher via 'passive drool' method and initially stored at −20◦C after collection in an insulated cooler box with reusable ice packs. The Main Researcher will transport the biospecimen to the Biotechnology Research Institute (BRI), Universiti Malaysia Sabah (UMS). Upon arrival to the lab, it should be stored at −80 ◦C until analysis is done (Paulino YC et al., 2020).

3.11.2 Sample Preparation

At the lab, a 100 µL aliquot of thawed saliva will be mixed with 10 µL of internal standard (IS) solution and 100 µL of acetonitrile in a 1.5 ml microcentrifuge tube. Then it will be vortexed at high speed to precipitate the BQ proteins. The mixture will then be diluted with 800 µL of 0.1% formic acid in MeOH: H2O (v:v = 1:1) and then later centrifuged at 13,500 x g for 5 min. The resultant supernatant will be transferred to High Performance Liquid Chromatography (HPLC) vials and subjected to Liquid Chromatography–Mass Spectrometry (LCMS) analysis (Franke AA et al,2015).

3.11.3 Chemicals

Arecoline hydrobromide, guvacine hydrochloride, nicotine, cotinine, hydroxycotinine, NNN, NAT, NNK, 4-(Methyl-d3-nitrosamino)-1-(3-pyridyl)-1-butanone (NNK-d3), nicotine-d4, cotinine-d3 and eugenol and o-eugenol will be purchased from Sigma-Aldrich (St. Louis MO), whereas Guvacoline hydrobromide, N-nitrosoguvacoline, Arecaidine Hydrobromide, Arecodine-d5, hydrobromide salt will be purchased from Medical Isotopes (Pelham, NH). All

solvents will be confirmed of LCMS grade and will be purchased from Fisher Scientific (Waltham MA) (Franke AA et al,2015).

3.11.4 Standards

The standard stock solutions of arecaidine, arecoline, guvacoline, guvacine, nicotine, cotinine, hydroxycotinine, N-nitrosoguvacoline, NNK, NNN, NAT, eugenol, and o-eugenol will be prepared in MeOH at concentrations of 10 µg/mL. The IS solution consisting of arecoline-d5, nicotine-d4, cotinine-d3, NNK-d3 will be prepared in MeOH at concentrations of 10 µg/mL.

The calibrator solutions will be made by mixing 100 µL standard stock solutions with 10 µL IS solution and 900 µL 0.1% formic acid in MeOH:H2O (1:1). Calibration curves will be generated by serially diluting standard stock solutions in 0.1% formic acid in MeOH:H2O (1:1) to obtain working concentrations of 0.1, 1, 10, 100, 200, 500, 1000, and 5000 ng/mL (Franke AA et al,2015).

3.11.5 LCMS analysis

The lab test will be run by staff at the Biotechnology Research Institute (BRI), Universiti Malaysia Sabah (UMS). The BRI lab is located at Kota Kinabalu, Sabah which is about 1 to 1.5 hours from the study site and precaution will be taken to deliver samples within 8 hours after collection due to the quick disappearance property of areca nut biomarkers after 8 hours of collection.

LCMS analysis will be carried out on a model Accela ultra HPLC system coupled to a Q Exactive Orbitrap Mass Spectrometer and a CTC PAL autosampler (all from Thermo-

Fisher, San Jose, CA). 10 µl of the above mixture will be injected into a Kinetex C18 column (150 x 3 mm, 2.6 µm, Phenomenex, Torrance CA) with a Phenomenex UHPLC C18 pre-column (3.0 mm i.d.).

Gradient elution will be performed at a flow rate of 300 µL /min using 10 mM ammonium hydroxide in H2O (A) and 10 mM ammonium hydroxide in MeOH (B) as follows: 0-15.0 min linear gradient from 65%A to 20%A; 15.0-20.0 min hold at 20%A; 20.0-20.1 min increase to 65%A then to equilibrate it for 5 minutes. Total HPLC time including equilibration will be around 25 minutes.

Mass analysis will be performed under positive and negative electrospray full scan mode, the conditions will be as follows: (+) ESI spray voltage 4.5 kv, capillary transfer temperature 350 ºC, (-) ESI spray voltage 3.5 kv, capillary temperature 320 ºC; and other parameters will be: HESI heater temperature 200 ºC, sheath gas flow rate 30 unit; auxiliary gas 5 unit, in-source CID 5 ev, scan range 100 ~ 1000. AGC target 1e6, maximum injection time 100 ms, resolution 35,000, microscan 1.

Quantitation of all analytes will be performed with Xcalibur™ software by extracting the within 5 ppm of the calculated exact masses as according: Arecoline and Arecoline-d5 at +ESI [M+H]+ 156.10191 and 161.13329; Guvacoline at +ESI [M+H]+ 142.08626, Guvacine at +ESI [M+H]+ 128.07061, Arecaidine at +ESI [M+H]+ 142.086, NNN at +ESI [M+H]+ 178.09749, NAT at +ESI [M+H]+ 190.09749, NNK and NNK-d3 at +ESI [M+H]+ 208.10805 and 211.12688, Nicotine and Nicotine-d4 at +ESI [M+H]+ 163.12297 and 167.14808, Cotinine and Cotinine-d3 at +ESI [M+H]+ 177.10224 and 180.12107, N-nitrosoguvacoline at +ESI [M+H]+ 171.07642, Hydroxycotinine at +ESI [M+H]+ 193.09715, and chavibetol at –ESI [M-H]- 163.07590 (Franke AA et al,2015).

3.12 Outcome of the Study

3.12.1 Primary Outcome Measures

Change in the number of participants who self-reported that they had quitted BQ chewing will be measured through follow-up questionnaire at day 22. This will represent the short-term cessation prevalence achieved by the study.

Change in the number of participants who self-reported that they had quitted BQ chewing will be measured through follow-up questionnaire at Month-3. This will represent the intermediate-term cessation prevalence (stay-quit) achieved by the study.

3.12.2 Secondary Outcome Measures

Levels of areca nut biomarkers in saliva samples will be tested via liquid chromatography mass spectrometry at day 22. The cut-off levels for areca nut biomarkers are arecoline (60 ng/mL), arecaidine (10 ng/mL), guvacoline (20 ng/mL), and guvacine (6 ng/mL) and cotinine (10 ng/mL). Biomarkers level above this cut-off points represent that participants are still practicing the habit and have not ceased the habit.

Levels of areca nut biomarkers in saliva samples will be tested via liquid chromatography mass spectrometry at Month-3. The cut-off levels for areca nut biomarkers are arecoline (60 ng/mL), arecaidine (10 ng/mL), guvacoline (20 ng/mL), and guvacine (6 ng/mL) and cotinine (10 ng/mL). Biomarkers level above this cut-off points represent that participants are still practicing the habit and have not ceased the habit.

3.13 Study Instrument

There are 2 study instruments used in this study; the baseline questionnaire and follow-up questionnaire which was described in 6.9.1.1 and saliva test was described in 6.10.

3.14 Data Collection

3.14.1 Baseline

The facilitators from the Kota Belud Dental Clinic staff will be trained and standardised for the conduct of this study. A training manual will be given to each facilitators. They will be briefed and their understanding on every item of the questionnaire and worksheets will be scrutinised and refined as intended by the study. Any difficult words identified by the facilitators will be changed to a simpler alternative. Translated words into Bajau dialect will be discussed and decided upon for standardisation.

From face-to-face interviews with the participants, information regarding demographics details and baseline information about BQ chewing behaviour, BQ composition, BQ dependency levels, reasons for chewing and readiness and self-perceived barriers to quit will be garnered. Face-to-face interview mode was chosen as a method to complete the questionnaire to obtain a better response rate and to minimise inaccurate response due to illiteracy issues and participant's poor comprehension due to age.

Participant's baseline saliva samples will be gained for biomarker comparison as a method to verify the intervention's self-reported effectiveness. Saliva samples collected will be transported within 2-3 hours to the lab facilities to be stored under -80 °C temperature. The transportation of these saliva samples will be monitored and carried out by the main researcher.

3.14.2 Follow up at 22-day (short term)

Information regarding participant's personal particular, participant's compliance, current chewing status, number of cut-down of habit by the participants (quid/day), total number of session attended and reasons if absent and the BQ composition if participants are still chewing will be gained through a face-to-face interview with a follow-up questionnaire.

Participant's 22-day saliva samples will be gained to evaluate the short term effectiveness of the intervention and to verify the self-reported outcomes. The levels of areca nut and cotinine biomarkers in saliva samples (via liquid chromatography mass spectrometry) will be evaluated. The cut-off levels for areca nut biomarkers are arecoline (60 ng/mL), arecaidine (10 ng/mL), guvacoline (20 ng/mL), and guvacine (6 ng/mL) and the cut-off levels for cotinine levels (10 ng/mL). Biomarkers level above this cut-off points represent that participants have still not ceased the habit.

3.14.3 Follow up at 1-month and 3-month

Information regarding participant's personal particulars, participant's current chewing status, number of cut-down of habit by the participants (quid/day) and the BQ composition if participants are still chewing will be taken through face-to-face interview with a follow-up questionnaire.

At 3-month, participants' saliva samples will be collected to evaluate the intermediate term effectiveness of the intervention and to verify the self-reported outcomes. The same cut-off levels of AN and cotinine will be used to represent the participant's cessation of their chewing habit.

3.15 Data Management and Analysis

3.15.1 Study variables and operational definition

The baseline questionnaire used in this study contains 6 parts and their variables are as described in the following tables:

Part A – Demographics

Conceptual Definition	Operational Definition	Type of Variable	Scale of Measurement
Age	Participant's age as of last birthday	Continuous/ Numerical	Years
Gender	Participant's gender	Categorical	1- Male 2- Female
Ethnic	Participant's ethnic background	Categorical	1- Bajau 2- Dusun 3- Irranun 4- Malay 5- Chinese 6- Indian 7- Others (specify)
Marital Status	Participant's current marital status	Continuous	1- Single 2- Married 3- Widowed/ Divorcee
Education Level	Participant's highest level of education	Categorical	1- University and above 2- Diploma 3- Certificate 4- STPM/ Matriculation 5- SPM 6- PMR 7- Primary school 8- No formal education
Occupation	Participant's occupation	Continuous	1- House maid 2- Unpaid worker or home maker 3- Self employed 4- Private employee

			5- Government or semi government employee
Monthly Income	Participant's monthly individual income	Continuous	1 < RM 500 2 RM 501 – RM 999 3 RM 1000 – RM 2999 4 RM 3000 - RM 4999 5 RM 5000 and above

Part B – BQ Chewing Behaviour & Other Concomittant Risk Habits (Maling TH, 2016 & Tahir Z et al., 2003)

Conceptual Definition	**Operational Definition**	**Type of Variable**	**Scale of Measurement**
Current Chewing Status	Did the participant chewed at least 1 BQ for the past 1 week	Categorical	0- No such habit 1- Habit currently practised 2- Past habit and now has stopped
Age started chewing	What was the age the participant started chewing BQ	Continuous/ Numerical	
Years have ceased the habit (for ex-chewers)	How long the ex-chewer has ceased the BQ habit	Categorical	1- A month ago 2- 3 months ago 3- About a year ago 4- Already more than 5 years
Frequency of chewing BQ	How often current BQ chewers chewed BQ	Categorical	1- Daily 2- Two-three times a week 3- Few times a month 4- I am an occasional betel quid chewer 5- Others, please specify
Number of BQ chewed per day	Number of BQ chewed by the participants in a day	Continuous/ Numerical	
Special practice (relevant to Kota Belud)	Do participants keep their BQ in their mouths overnight	Categorical	1- Yes 2- No

Past quit attempts	If the participants have attempted quitting chewing before in their life	Categorical	1- Yes 2- No
Number of past quit attempts	The number of attempts participants have tried to cease the behaviour in the entire lifetime	Continuous/ Numerical	
Current Smoking Status	Did the participant smoke at least 1 cigarette for the past 1 week	Categorical	0- No such habit 1- Habit currently practised 2- Past habit and now has stopped
Frequency of smoking	How often does the current smoker smokes	Categorical	1- Daily 2- Two-three times a week 3- Few times a month 4- I am an occasional smoker 5- Others, please specify
Current Drinking Status	Did the participant drink at least 1 pint of alcohol for the past 1 week	Categorical	0- No such habit 1- Habit currently practised 2- Past habit and now has stopped
Frequency of alcohol drinking	How often does the current alcohol drinker drinks	Categorical	1- Daily 2- Two-three times a week 3- Few times a month 4- I am an occasional drinker 5- Others, please specify
Medical problems	Medical conditions of the participant	Categorical	1- Yes (specify) 2- No

Part C – BQ Composition (Tahir Z & Doss JG, 2003)

Conceptual Definition	Operational Definition	Type of Variable	Scale of Measurement
Betel quid composition	The composition of BQ chewed by participants	Categorical	a. Areca nut b. Tobacco c. Betel leaf d. Lime e. Gambir f. Others (please specify)

Part D – Reasons for betel-quid chewing scale (RBCS) (Little MA et al., 2014)

Conceptual Definition	Operational Definition	Type of Variable	Scale of Measurement
Construct 1: Reinforcement			
1. I like the taste	Participants chews BQ because they enjoy the quid's taste	Categorical	0 = No 1 = Yes
2. I like to have something in my mouth at all times	Participants chews BQ because they are fond of having something in the mouth at all time period	Categorical	0 = No 1 = Yes
Construct 2: Social/cultural			
3. All of my friends chew	Participants chews BQ because all of their friend circle chews it as well	Categorical	0 = No 1 = Yes
4. My family members chew	Participants have family members who chews BQ (children, brothers, sisters, parents, grandparents, aunts, uncles, and other family members)	Categorical	0 = No 1 = Yes

5. It's rude not to chew	Participants chews BQ because it was considered rude or an insult if they didn't	Categorical	0 = No 1 = Yes
6. People will not respect me if I don't chew	Participants chews BQ for respect from surrounding social circle	Categorical	0 = No 1 = Yes
Construct 3: Stimulation			
7. It relaxes me	Participants feels relax as they chew BQ	Categorical	0 = No 1 = Yes
8. It gives me energy	Participants claims chewing BQ gives them energy	Categorical	0 = No 1 = Yes
9. It helps me make decisions	Participants feels chewing BQ helps them to make decisions	Categorical	0 = No 1 = Yes
10. I like the way it makes me feel	Participants claims likes the feeling of chewing a BQ	Categorical	0 = No 1 = Yes
Others			
11. Insult if do not chew BQ in social situations	Participants will be considered insulting a social situation if he or she didn't chew	Categorical	0- Never 1- Seldom 2- About Half the Time 3- Usually 4- Almost always
12. Importance of chewing betel quid was in the social situations	Participants feels it's important to chew BQ during following functions (birthdays, fiestas, anniversaries (of deaths), parties, rosaries, and working)	Categorical	0 = Not important 1 = Slightly Important 2 = Moderately Important 3= Important 4 = Extremely important

Part E – Betel Quid Dependency Scale (T.A. Herzog et al., 2014)

Conceptual Definition	Operational Definition	Type of Variable	Scale of Measurement
Domain 1: Physical and psychological urgent need			
1. Can't go on without betel nut/quid	Participant have urgent need to chew BQ	Categorical	0-No 1-Yes
2. Difficulty concentrating after reducing use	Participants have difficulty in concentration after reducing BQ chews in a day	Categorical	0-No 1-Yes
3. Experienced depression or drowsiness	Participant experiencing depression or drowsiness as craving or withdrawal symptoms	Categorical	0-No 1-Yes
4. Strong craving after reducing/stopping to chew	Participant experiencing strong craving after reducing number of chews or ceasing the habit	Categorical	0-No 1-Yes
5. Spend time to find when not available	Participants spend a considerable amount of time to search for BQ if it's not available	Categorical	0-No 1-Yes
6. Travel great distance to find when not available	Participants travel a considerable amount of distance to search for BQ if it's not available	Categorical	0-No 1-Yes
7. Felt agitated, irritated, or anxious after reducing	Participant feels agitated, irritated, or anxious after reducing chews per day	Categorical	0-No 1-Yes

Factor 2: Increasing dose			
8. Trouble stopping once started chewing	Participant face difficulty to stop chewing once started the habit	Categorical	0-No 1-Yes
9. Ever chewed non-stop	Participant's past experience whether he or she has chewed BQ non-stop in a day	Categorical	0-No 1-Yes
10. Increased the amount of use after first use	Participants' past experience whether they increased the amount of BQ ingredients or the number of chews after first use	Categorical	0-No 1-Yes
11. Felt the need to increase amount of use periodically	Whether participants have ever felt the need to increase the number of chews or amount of BQ ingredients periodically	Categorical	0-No 1-Yes
12. Often chewed betel nut/quid more than expected	Participant's experience whether he or she often chewed BQ more than expected or routinely practiced	Categorical	0-No 1-Yes
Factor 3: Maladaptive use			
13. Continue chewing after teeth loose nor wiggle	Participant's experience of continuing chewing BQ even when teeth were loose	Categorical	0-No 1-Yes
14. Continue chewing if you had sensitive teeth	Participant's experience of continuing chewing BQ even when they had sensitive teeth	Categorical	0-No 1-Yes
15. Continue chewing if experienced mouth ulcers	Participant's experience of continuing chewing BQ even when they had mouth ulcers	Categorical	0-No 1-Yes
16. Reduced or given up activities because of chewing	Participant's experience of reducing or giving up other activities to chew BQ	Categorical	0-No 1-Yes

Part F – Readiness & Self-Perceived Barriers To Quit Habit (Brown RA, 2003)

Conceptual Definition	Operational Definition	Type of Variable	Scale of Measurement
1. Readiness to quit chewing habit	Participant's readiness to quit behaviour	Categorical	0- Will continue and accept the consequences 1- Attempted to quit but does not think it will succeed 2-Will reduce or modify habit 3- Have great determination to quit and thinks will succeed
2. Self -perceived barriers in quitting chewing habit	Participant's self-thought barriers or difficulties in quitting chewig behaviour	Categorical	1- Without BQ, I will be anxious 2- Without BQ, I will feel down, sad and depressed 3- Without BQ, I will feel easily irritable 4- Without BQ, I will gain weight 5- Without BQ, I will not be respected in my community/family 6- Without BQ, I will lose my social circle 7- It's hard to quit, I have tried in the past 8- I have thoughts to quit but I don't know how to quit 9- I don't think it is important to quit 10- Other, please specify: _____

3.15.2 Data Entry

All data collected will be entered into a Microsoft Excel database, cleaned and then exported to Statistical Package for Social Sciences (SPSS) version 29.0. Descriptive analysis through means and standard deviation will be reported for continuous variable and in the form of percentage for categorical variables and individual items in each domain. A mean and standard deviation also will be calculated for the aggregated domain score. Data of participants that attended all sessions will be analyzed for the cessation rate measurements.

3.16 Ethic Approval & Application

The ethical approval of the study was obtained from the Medical Ethics Committee, Faculty of Dentistry, UM [DF CO2301/0007 (P)] on 16th January 2023 as attached in Appendix. The study will also gain the ethical approval from the Medical Research and Ethics Committee (MREC) of the National Medical Research Registry (NMRR), National Institutes of Health (NIH), Malaysia.

3.17 Participant Information Sheet and Informed Consent

Participant information sheet (PIS) and informed consent (IF) will be a prerequisite before participants admitted into the study on the screening day. After going through the PIS, participants who refused to provide consent will not be admitted into the study. Nevertheless, the benefits of this study will be emphasized to them.

3.18 Other Related Approvals

An application for permission to conduct the study has been submitted to the Principle Director of Oral Health Program (MOH) Malaysia on 26th January 2023. Thereafter an application will be made to the Sabah State's Deputy Health Director (in-charge of Dental Division).

Upon securing the approvals, a briefing with the aid of Microsoft Power Point slide presentation will be given to all relevant stakeholders of this study to garner their support and cooperation towards this meaningful and noble study.

3.19 Funding

The study will be funded by the Dental Postgraduate Research Grant, University Malaya and other research grants will also be sought after to lessen the high expenditure that will be incurred by the salivary LCMS lab tests and flight travels.

3.20 Data Privacy & Confidentiality

Every reasonable precaution will be taken to ensure the privacy and confidentiality of all information taken. All personal information that is collected will be kept with utmost confidentiality and will only be used for study purposes only.

3.21 Record Keeping, Data Access & Storage

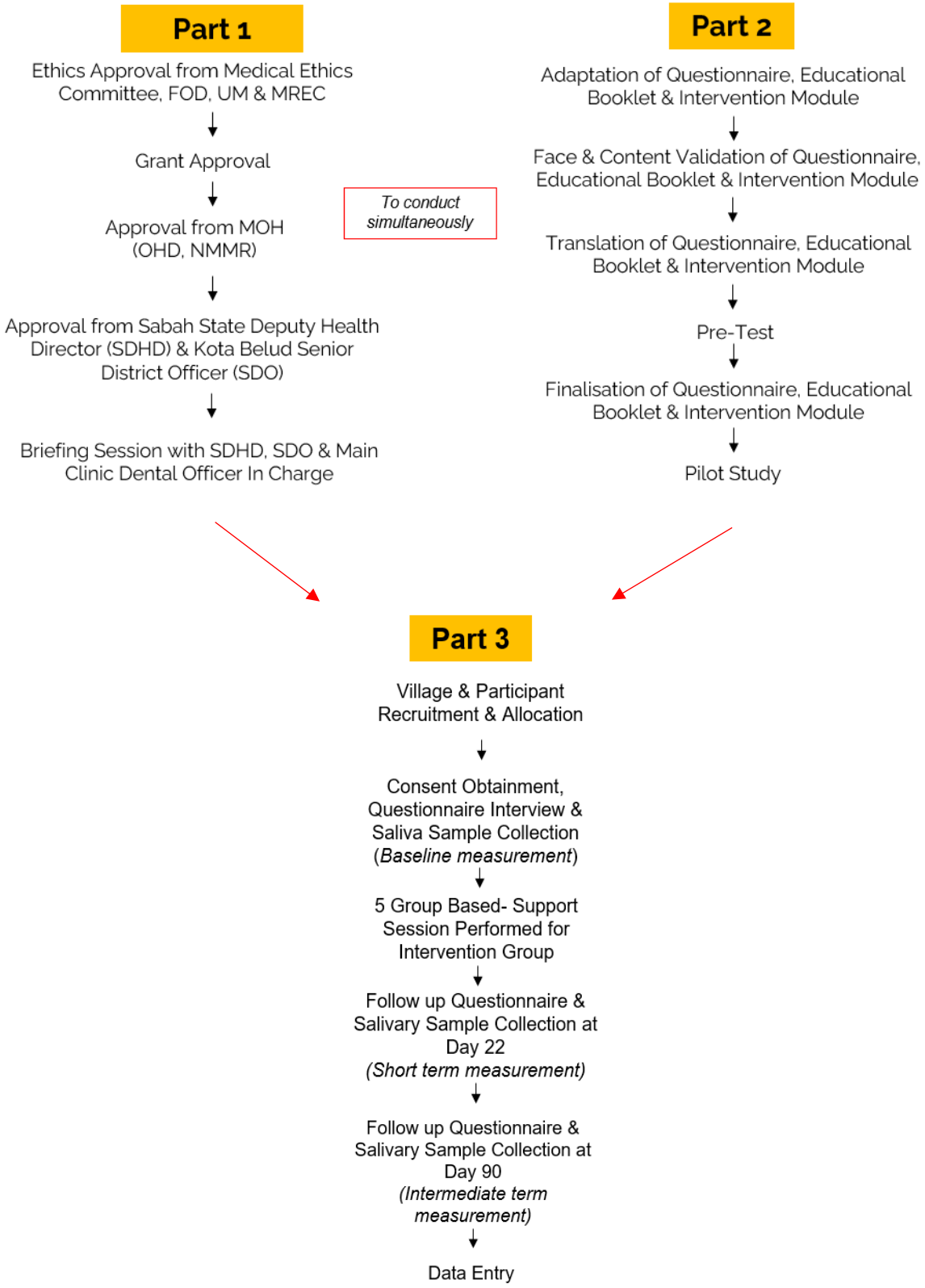
All softcopy research data will be kept in the stored in an external hard drive encrypted with a strong password. Extra measures will be taken to keep the hardcopy data safe and confidential in a locked file cabinet in the Department's room.

Only principal investigator and co-investigators will have access to participant's research data. Study findings will be shared with participants upon request. All data will be kept for a minimum of 3 years after study completion and hence after destroyed.

3.22 Publication Policy

Research findings would be disseminated through academic papers, conference presentations or other means. Extra care would be taken to anonymize any identifiable information prior to dissemination.

3.23 Flow Chart of Research Activities



3.24 Gantt Chart of Research Activities

	YEAR 2											
Year	**2022**								**2023**			
Task	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**
Conceptualization of study	√	√										
Further conceptualization on the research methodology			√									
Research proposal preparation & defense				√	√	√						
Application for Ethics, Grants and to MOH & other parties							√	√	√	√		
Phase 1 **Adaptation** of Questionnaire, Educational Booklet, and Intervention Module											√	
Validation of the Adapted Questionnaire, Educational Booklet, and Intervention Module											√	
Translation of the Validated Questionnaire, Educational Booklet, and Intervention Module												√
Training of the Main Researcher					√	√	√	√	√			√

	YEAR 3									
Year	**2023**								**2024**	
Task	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**
Phase 2 **Village selection & recruitment** (Inclusive of meeting with village head for Pre-test Village)	√									
Pre-test	√									
Recruitment & Training of the Facilitators	√									
Meeting with Village Head & Preparation for Pilot Test	√									
Pilot test		√								
Training of the Facilitators			√							
Phase 3 **Promotional Initiatives**			√							
Implementation of the study & Data collection			√	√	√					
Data entry						√				
Data analysis						√				
Report writing							√	√		
Manuscript writing									√	
Report submission										√

3.25 Milestones and Dates

Activities	Dates	Progress
Research Proposal Presentation & Defence	11th October 2022	Completed
Application for Ethics Approval		
i) Medical Ethics Committee, Faculty of Dentistry, University of Malaya	23rd November 2022	Completed
ii) Medical Research and Ethics Committee (MREC) of the National Medical Research Registry (NMRR), National Institutes of Health (NIH), Malaysia	January-February 2023	*In Progress*
Application for Grants to Fund Study		
i) Dental Postgraduate Research Grant (DPRG) 2022	December 2022	Completed *(Waiting for call of meeting letter)*
ii) NIH Grant on Special Interest (NOSI): Dissemination and Implementation Science for Cancer Prevention and Control in Low Resource Environments (Notice Number: NOT-CA-22-038)	January-February 2023	Completed (Had a brief meeting with NIH Global Health Program Director on 2.2.23)
iii) NIH Malaysia	February 2023	*In Progress*
Application for Permission to Conduct Study and Usage of Facility and Manpower		
i) Principle Director of Oral Health Program (MOH) of Malaysia ii) Sabah State's Deputy Health Director (in-charge of Dental Division) iii) Kota Belud District Dental Officer	January-February 2023	Completed *(Awaiting reply)*

Activities	Dates	Progress
Phase 1		
Cross-cultural adaptation of Questionnaire, Educational Booklet, and Intervention Module	March 2023 (Week 1-2)	
Validation of the Adapted Questionnaire, Educational Booklet, and Intervention Module	March 2023 (Week 3-4)	
Translation of the Validated Questionnaire, Educational Booklet, and Intervention Module	April 2023 (Week 1-2)	
Finalisation of Translated Questionnaire, Educational Booklet & Intervention Module	April 2023 (Week 3-4)	
Training of the Main Researcher		
1. Questionnaire Design and Validation Workshop ~	29th September 2022	Completed
2. Kuala Lumpur Nicotine Addiction International Conference	3rd October 2022	Completed
3. Qualitative Research Methodology & Data Analysis Using Atlas Ti V22 Workshop	12-13th November 2022	Completed
4. Effective Thesis Writing	29th & 30th November 2022	Completed
5. Cognitive Behavioural Therapy (CBT) on Substance Abuse	29th & 30th November 2022	Completed
6. One-to One Training with BENIT Principal Researchers (AP Thaddeus Herzog & AP Yvette Paulino)	April 2023	*In Progress*
Phase 2		
Village selection & recruitment *(Inclusive of meeting with village head for Pre-test Village)*	May 2023 (Week 1)	
Pre-test	May 2023 (Week 2)	

Activities	Dates	Progress
Recruitment & Training of the Facilitators Meeting with Village Head & Preparation for Pilot Test	May 2023 (Week 3) May 2023 (Week 4)	
Pilot test Modification to the Questionnaire, Educational Booklet, Intervention Module & others based on findings of Pilot Test	June 2023 (Week 1-3) June 2023 (Week 4)	
Training of the Facilitators	July 2023 (Week 1)	
Phase 3 Promotional Initiatives	July 2023 (Week 1)	
Implementation of the study & Field Data collection	July-September 2023	
Data entry	October 2023 (Week 1-2)	
Data analysis	October 2023 (Week 3-4)	
Report writing	November-December 2023	
Candidature Defence	January 2024	
Manuscript writing	January 2024	
Report submission	February-March 2024	

4.0 EXPECTED RESULTS/BENEFIT

i. Novel theories/New findings/Knowledge

This study would be able to provide new and updated knowledge on the demographics of BQ chewers, BQ chewing behaviours, BQ composition, BQ dependency levels, reasons for BQ chewing, the readiness and self-perceived barriers to cease BQ habit among Bajau BQ users in selected high-risk communities in Kota Belud, Sabah, Malaysia.

Another crucial new finding that can be garnered from this study is the usage of saliva bio verification procedures to verify the self-reported outcomes from the BQ cessation program conducted within the high-risk communities. This will be the first conducted in Malaysia thus far.

ii. Research Publications

A minimum of 2 research publications are targeted to be produced by this study. A paper on the cross-culturally adapted BQ cessation program and its pilot test findings. Another paper on the implementation of the BQ cessation program and verification of the program's effectiveness with a saliva test.

iii. Specific or Potential Applications

This study will significantly facilitate the Oral Health Program of the Ministry of Health (MOH), Malaysia and other organisation with the an introduction of the first BQ cessation program for Malaysian high risk communities which have been long neglected.

In the long run, through continuous and wider execution of this cesation program, it could help to reduce the high prevalence of BQ chewing practices in Malaysia. Apart from that, the

BQ users would also be finally able to experience a formal cessation program to curb their addictions.

iv. Intellectual Properties (if any)

A newly adapted Betel Quid Cessation Program for high-risk communities in Malaysia.

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6.0 APPENDIX

Appendix A Patient Information Sheet

PARTICIPANT INFORMATION SHEET

Please read the following information carefully. We will be glad to assist you with any questions you may have throughout this study.

Study Title

Cross-Cultural Adaptation of a Betel Quid Cessation Program and Evaluation of Its Effectiveness in A Malaysian High-Risk Community

Introduction

Betel quid chewing is known as one of the most common causes of oral cancers in Malaysia (OHD, 2018) and more than 50% of the patients present at the later stage of the disease which is at Stage III and IV. Besides oral cancer, chewing betel quid too can result in many other diseases such as submucous fibrosis, periodontal disease, malnutrition, gastric ulcer, hypertension, coronary artery spasm, poor quality of blood, difficulty of breathing, placental damage, preterm birth and many more.

Betel quid chewing habit was also recognised by the World Health Organisation (WHO, 2010) to be a habit that binds the chewers with a dependency syndrome. Hence, spontaneous withdrawal or cessation of the habit might not be possible or achievable by just a few brief advises. Thus, a cessation program is highly required. Through a cessation program, participants (chewers) will be given adequate knowledge and awareness and be guided how to quit this behaviour gradually and successfully.

Till to date, there is no cessation program developed or adapted for the betel quid chewers in Malaysia. Thus, it is timely for Malaysia to adapt a cessation program for the high-risk groups in Malaysia to help them change their behaviour and achieve a healthier life.

What is the purpose of this study?

This is an experimental research study. The aim of this study is to cross-culturally adapt a betel quid cessation program for a Malaysian high-risk community and to evaluate the effectiveness of the adapted program using a combination of self- reported outcomes and salivary biomarkers measurements.

What are the procedures to be followed?

1) You will be required to complete a set of questionnaires. You will be guided by an interviewer to complete it. The questionnaire will comprise of:
   a) Demographic details
   b) Composition of betel quid chewed, current chewing behaviour and chewing history
   c) Reason(s) for betel quid chewing
   d) Betel quid dependency level
   e) Readiness to quit chewing habit
   f) Self-perceived barriers to quit chewing habit

2) You will be required to join 2-5 sessions of support group within 21 days based on your allotted appointment schedules.

3) You will be required to provide a sample of your saliva at the end of few sessions for chemical testing. Around 1-2mL of your saliva sample will be collected in a 20 mL, conical shape tubes via passive drool method which will later be stored in an insulated cooler box.

4) No intra-oral clinical examination will be carried out in this study.

Who should not enter the study?

1) Non-Malaysian citizen
2) Those who cannot read or write in Malay or Bajau
3) Participants below 18 years old
4) Participants who are not willing to quit betel quid chewing habit during the time of study
5) Women who are pregnant or nursing at the time of study
6) Individuals with psychiatric illness or special social situations that would limit their compliance with study requirements

A total of 92 participants are needed for this study. The study will be conducted within the month of April till December 2023, but participants are only required to attend the session based on appointment dates given.

What will be the benefits of the study?

(a) To participant?

You will be able to increase your knowledge and awareness towards betel quid chewing habit and be able to cease the habit. By an early cessation, the negative effects of betel quid chewing on health can be prevented and participants can lead a healthier life. A monetary token of RM20-RM50 will be given to participants that comply and attend to all study visits.

(b) To the investigator

The investigators will be able to introduce a cessation program that will benefit the high-risk communities in Malaysia. This cessation program can later be utilised by the stakeholders in the Ministry of Health (MOH), Malaysia to cater for other high-risk populations in Malaysia.

(c) **What are the possible risks / complications / adverse effects that may happen?**

There is no risk or drawback associated in participating with this study.

Can I refuse to take part in the study?
Your participation is totally voluntary. You can choose to refuse to participate in this study and your refusal will be treated with respect. It will not affect any medical or dental services that you are entitled in the public hospitals or clinics.

Who will have access to my research data, and will it be kept confidentially?
Only principal investigator and co-investigators will have access to participant's research data.
All research data will be kept in the researchers' laptop and their cloud account. Extra measures will be taken to keep the hardcopy data safe and confidential in the researcher's locker in the Department's room.

What will happen to the results of the research study?
Research findings would be disseminated through academic papers, conference presentations or other means. Extra care would be taken to anonymize any identifiable information prior to dissemination. Study findings will be shared with participants upon request.

Who shall I contact if I have additional questions/complications during the course of the study?

(1) Investigator's Name: Dr. Mary Melissa A/P Sarimuthu
Mobile No.: 019-6525710
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Official email address: 17202163@siswa.um.edu.my

(2) Investigator's Name: Professor Dr. Jennifer Geraldine Doss
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(3) Investigator's Name: Associate Prof. Dr. Amer Siddiq Bin Amer Nordin
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Appendix B

UNIVERSITI MALAYA
PUSAT PERGIGIAN

CONSENT BY PARTICIPANT FOR RESEARCH
FACULTY OF DENTISTRY, UM, K.L.

I, …… Identity Card No ……
(Name of participant)

of ……
(Address)
hereby agree to take part in the research specified below:

Title of Study:

Cross-Cultural Adaptation of a Betel Quid Cessation Program and Evaluation of Its Effectiveness in A Malaysian High-Risk Community

The nature and purpose of the research has been explained to me by ……
(*Name & designation of doctor*)
and interpreted (when necessary) by ……..... to the best of his/her ability
(*Name & designation*)
in …… (*specify language*). After knowing and understanding all the possible advantages and disadvantages of this research, I voluntarily consent of my own free will to participate.

I understand that I can withdraw from this research at any time without assigning my reason whatsoever.

Signature …… Date ……
(*Participant*)

IN THE PRESENCE OF

Name ……,

I/C No. ……., Position ……...

Signature …… Date .....
(Witness for signature of participant)

I confirm that I have explained to the participant the nature and purpose of the above-mentioned research.

Signature …….. Date ……....
(Attending doctor)

Appendix C – Baseline Questionnaire

ID				

JABATAN KESIHATAN PERGIGIAN MASYARAKAT DAN PENCEGAHAN KLINIKAL

Cross-Cultural Adaptation of a Betel Quid Cessation Program and Evaluation of Its Effectiveness in A Malaysian High-Risk Community

Dr. Mary Melissa A/P Sarimuthu, Professor Dr. Jennifer Geraldine Doss,
Associate Prof. Dr. Amer Siddiq Bin Amer Nordin

BASELINE QUESTIONNAIRE	*Office use*

***Date of Program*:** _____

Name (*as in Identity Card*)**:** _____

Address *(current home address)*: _____

_____

***Telephone No.*:** _____

Identity Card No.: _____

SECTION A: DEMOGRAPHICS
Please answer all the questions in the given space or tick (√) in the given box

Participant's Information:

1. Age *(as on last birthday)*: _____
2. Gender
   a. Male ☐
   b. Female ☐
3. Ethnic:
   a. Malay ☐
   b. Chinese ☐
   c. Indian ☐
   d. Bajau ☐
   e. Dusun ☐
   f. Irranun ☐
   g. Others, please specify: ☐
   _____

4. Marital Status

   a. Single ☐

   b. Married ☐

   c. Widow/ *Widower/ Divorcee* ☐

5. Highest level of education

   a. Degree equivalent or higher ☐

   b. Diploma or equivalent ☐

   c. Certificate or equivalent ☐

   d. STPM/ Matriculation or equivalent ☐

   e. SPM or equivalent ☐

   f. PMR or equivalent ☐

   g. Primary school ☐

   h. No formal education ☐

6. Occupation

   a. Government or semi government employee ☐

   b. Private employee ☐

   c. Self employed ☐

   d. Unpaid worker or home maker ☐

   e. House maid ☐

7. Individual's monthly income

   a. < RM 500 ☐

   b. RM 501 – RM 999 ☐

   c. RM 1000 – RM 2999 ☐

   d. RM 3000 - RM 4999 ☐

   e. RM 5000 and above ☐

SECTION B: CHEWING BEHAVIOUR & OTHER CONCOMITTANT RISK HABITS (Maling TH & Doss JG, 2016)

The section aims to determine the current chewing behavior, other concomitant risk habits and consequence of chewing behavior (medical conditions) of the betel quid chewers

1. What is your current betel quid chewing status? a. No such habit (proceed to Q9) b. Habit currently practiced c. Past-habit and now has stopped	☐ ☐ ☐
2. At what age did you start chewing betel quid? ☐☐ Years old	☐
3. If you are an ex-chewer, how long ago have you stopped chewing betel quid? a. A month ago b. 3 months ago c. About a year ago d. Already more than 5 years	☐ ☐ ☐ ☐
4. For current chewer, how often do you chew betel quid? a. Daily b. 2-3 times a week c. Few times a month d. I am an occasional betel quid chewer e. Others, please specify: _____	☐ ☐ ☐ ☐
5. How many quid(s) do you chew in a day? ☐☐	☐
6. Do you keep the betel quid in your mouth overnight? a. Yes b. No	☐
7. Have you tried to quit chewing habit before? a. Yes b. No	☐ ☐
8. If you have tried quitting the chewing habit before, how many times did you tried? ☐☐	☐
9. What is your current smoking status? a. No such habit (proceed to Q11) b. Habit currently practiced c. Past-habit and now has stopped	☐ ☐ ☐
10. For current smoker, how often do you smoke cigarette? a. Daily b. 2-3 times a week c. Few times a month d. I am an occasional smoker e. Others, please specify: _____	☐ ☐ ☐ ☐
11. What is your current alcohol drinking status? a. No such habit (proceed to Q13) b. Habit currently practiced	☐ ☐ ☐

c. Past-habit and now has stopped	
12. For current drinker, how often do you drink alcohol? a. Daily ☐ b. 2-3 times a week ☐ c. Few times a month ☐ d. I am an occasional drinker ☐ e. Others, please specify: _____ ☐	☐ ***B12***
13. Do you have any medical condition (s)? a. Yes (Please specify): _____ b. No	☐ ***B13***

SECTION C: BETEL QUID COMPOSITION PROFILE (Tahir Z., Doss JG & Jaafar N, 2003)

The section aims to assess the betel quid composition practiced by the chewers

1. What is (are) the ingredients that you use in your betel quid? a. Areca nut ☐ b. Tobacco ☐ c. Betel leaf ☐ d. Lime ☐ e. Gambir ☐ f. Others ☐ (If yes, please specify: _____)	☐ ***C1***

SECTION D: REASONS FOR BETEL-QUID CHEWING SCALE (RBCS) (Little MA et al., 2014)

The section aims to assess the reasons the chewers chew betel quid

1. Did you began chewing betel quid because of the following:			☐ ***D1***
	Yes	No	
a. You like the taste	☐	☐	
b. You like to have something in your mouth at all times	☐	☐	
c. All of your friends chew	☐	☐	
d. Your family members chew	☐	☐	
e. It's rude not to chew	☐	☐	
f. People will not respect you if you do not chew	☐	☐	
g. It relaxes you	☐	☐	
h. It gives you energy	☐	☐	
i. It helps you make decisions	☐	☐	
j. You like the way it makes you feel	☐	☐	
2. Which of your other family members that chews betel quid? *(Only for those who answered 'Yes' for 1d)* a. Children ☐ b. Brothers ☐ c. Sisters ☐			☐ ***D2***

d. Parents ☐
e. Grandparents ☐
f. Aunts ☐
g. Uncles ☐
h. Other family members ☐

3. Is it considered an insult if you do not chew betel quid in social situations? ☐ ***D3***
   a. Never ☐
   b. Seldom ☐
   c. About Half the Time ☐
   d. Usually ☐
   e. Almost always ☐

4. How important is chewing betel quid in the following situations: ☐ ***D4***

	Not important	Slightly important	Moderately important	Important	Extremely important
a. Birthdays	☐	☐	☐	☐	☐
b. Fiestas	☐	☐	☐	☐	☐
c. Anniversaries/deaths	☐	☐	☐	☐	☐
d. Parties	☐	☐	☐	☐	☐
e. Working	☐	☐	☐	☐	☐

SECTION E: BETEL QUID DEPENDENCY SCALE (T.A. Herzog et al., 2014)

The section aims to assess the betel quid dependency level among the chewers

1. Have you ever felt that you cannot go on without betel quid? ☐ ***E1***
   a. Yes ☐
   b. No ☐

2. Have you found yourself having trouble stopping chewing betel quid once you started? ☐ ***E2***
   a. Yes ☐
   b. No ☐

3. Have you ever chewed betel quid non-stop? ☐ ***E3***
   a. Yes ☐
   b. No ☐

4. Have you experienced a strong craving for betel quid after you reduce or completely stopped chewing betel quid? ☐ ***E4***
   a. Yes ☐
   b. No ☐

5. Whenever you want to chew betel quid but it is not available, would you spend a lot of time to find it? ☐ ***E5***
   a. Yes ☐
   b. No ☐

6. Whenever you want to chew betel quid but it is not available, would you take extra steps and travel a great distance trying to buy it? For example, even suffer from fatigue by a long journey a. Yes ☐ b. No ☐	☐ ***E6***
7. Have you felt agitated, irritated, or anxious after you reduce or completely stopped chewing betel quid? a. Yes ☐ b. No ☐	☐ ***E7***
8. Have you experienced difficulty in concentrating or focusing after you reduce or completely stopped chewing betel quid? a. Yes b. No ☐	☐ ***E8***
9. Have you experienced depression or drowsiness after you reduce or completely stopped chewing betel quid? a. Yes ☐ b. No ☐	☐ ***E9***
10. Do you have a situation that the amount of betel quid is gradually increased every time you chew it from the first time you experienced it? a. Yes ☐ b. No ☐	☐ ***E10***
11. Have you felt the need to increase the amount of betel quid chewing periodically in order to achieve a pleasant or refreshing effect? a. Yes ☐ b. No ☐	☐ ***E11***
12. Have you often found yourself chewing more betel quid that expected and/or spending more time chewing betel quid than expected? a. Yes ☐ b. No ☐	☐ ***E12***
13. Would you continue chewing betel quid if you find your teeth loosened or wiggled? a. Yes ☐ b. No ☐	☐ ***E13***
14. Would you continue chewing betel quid if you have sensitive teeth (to hot or cold food)? a. Yes ☐ b. No ☐	☐ ***E14***
15. Would you continue chewing betel quid if you experience canker sores or mouth ulcers? a. Yes ☐ b. No ☐	☐ ***E15***
16. Have you reduced or given up any of your social, work, or leisure activities because of betel quid chewing? a. Yes ☐ b. No ☐	☐ ***E16***

SECTION F: READINESS & SELF PERCEIVED BARRIERS TO QUIT CHEWING HABIT (Maling TH & Doss JG, 2016 & Brown RA, 2003)

The section aims to assess the readiness and self-perceived barriers of chewers to quit their betel chewing habits

1. What is your readiness to quit your betel quid chewing habit now?
   a. Have great determination to quit and thinks will succeed ☐
   b. Will reduce or modify habit ☐
   c. Attempted to quit but does not think it will succeed ☐
   d. Will continue and accept the consequences ☐

☐ ***F1***

2. What are your barriers in quitting betel quid chewing habits?
   a. Without BQ, I will be anxious ☐
   b. Without BQ, I will feel down, sad and depressed ☐
   c. Without BQ, I will feel easily irritable ☐
   d. Without BQ, I will gain weight ☐
   e. Without BQ, I will not be respected in my community/family ☐
   f. Without BQ, I will lose my social circle ☐
   g. It's hard to quit, I have tried in the past ☐
   h. I have thoughts to quit but I don't know how to quit ☐
   i. I don't think it is important to quit ☐
   j. Other, please specify: _____ ☐

☐ ***F2***

Appendix D - Trigger monitoring logs

TRIGGER MONITORING LOGS

BETEL QUIDS	TIME	HOW DO YOU FEEL?								WHAT ARE YOU DOING?
		Happy	Sad or Depressed	Relaxed	Bored	Anxious	Angry	Tired	Frustrated	
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										

Appendix E - Trigger management worksheet

TRIGGER MANAGEMENT WORKSHEET

How did you manage your triggers for betel quid chewing this week?

1. Continue to keep a record of your triggers for betel quid chewing and the strategies you used to deal with them.
2. This week, reduce the number of betel quids you chewed by 10 % of what you chewed last week and chew only the allowed quantity and record the triggers and strategies used to deal with it.

TRIGGER	STRATEGIES

Appendix F - Arecoline Fading Worksheet

ARECOLINE FADING WORKSHEET

	Day 1	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**	**Average number chewed per week**	**Percent-age of reduction**
Week 1									
Week 2									
Week 3									
Week 4									

*****To reduce 1 quid within 2-3 days OR reduce 10% of BQ within 2-3 days

Example of Betel Quid Rate Reduction Chart for 3 Weeks

Week / Day	1	2	3	4	5	6	7	Total Reduction
Week 1	10%		10%		10%			30%
Week 2	10%		10%		10%			60%
Week 3	10%		10%		20%			100%

Appendix G – Brief Relaxation Exercise

BRIEF RELAXATION EXERCISE

The goal of this relaxation exercise is to learn the difference between muscle tension and relaxation. Once that distinction is mastered, it's much easier to evoke a feeling of relaxation, even in stressful settings!

Here's how to get started:

1) Find a quiet, darkened room. Lie on your back or sit in a comfortable, straight- backed chair.
2) Slowly draw as much air as you can into your chest and release it. Do this three or four times. Then let your breathing go back to its normal rhythm. Listen to it.
3) Starting with your face, you are going to tighten and relax groups of muscles as you move down the body. Scrunch your face up tightly for 5 seconds, then relax it. Do this for each of these muscle groups: the neck and shoulders, the arms, the stomach and chest, the legs, and the feet. As each part of your body relaxes, let it go limp. Feel the tension leave your body. You should feel like you are floating in space.

Appendix H – Brief Coping Skills

BRIEF COPING SKILLS TRAINING

Chewing doesn't just happen automatically, though it might seem like it sometimes. There are usually triggers or events that cause you to have an urge and then to chew. These triggers can be feelings, thoughts, or situations. There are three types of *behavioral* or habit changing strategies you can use to cope with these triggers, to break up the chain of events that lead to chewing:

1. Avoid the trigger. Avoiding the trigger obviously can be the most powerful strategy. If you are not around the trigger, you will not have an urge and you will not chew. For example, if you know that having a cup of coffee is a big trigger for you, then not having a cup of coffee will decrease your desire for a betel quid. However, sometimes avoiding a trigger is not always the most practical strategy; if waking up in the morning is a trigger, you can't simply avoid waking up, as much as you might like to sometimes. That's why there are two additional types of strategies to help you manage your chewing triggers.

2. Alter the trigger situation. Think of your triggers to chew as very fixed parts of your daily routine—anything that you can do to alter that routine can help you to manage your chewing urges. What you're doing is essentially taking control of your environment so that you can control your chewing. For example, let's take that cup of coffee as a trigger. If you always drink that cup of coffee in the same place using the same cup at the same time of the day, change any one or all of those parts of the routine: change the cup you use, drink your coffee in a different chair or part of the house. The key with altering a trigger is to be creative. Use it as an opportunity to challenge yourself to outsmart the environment to give you control of your chewing.

3. Substitute something else for the betel quid when you encounter the trigger. This can be as simple as putting a piece of carrot or hard non-cariogenic food in your mouth when you want a betel quid. Again, think of this as an opportunity to be creative.

Another type of coping strategy is **a *cognitive*** strategy that involves changing your thoughts or telling yourself things so that you will not want to chew. These self-statements can include

a. Reasons you want to quit
b. Benefits of quitting
c. Statements of determination (e.g., "I can do it")
d. Delay statements (e.g., "only five more minutes").

Appendix I – Non BQ Chewing Game Plan : Lifestyle Change Worksheet

NON-BQ CHEWING GAME PLAN LIFESTYLE CHANGE WORKSHEET

List specific answers to some general lifestyle changes that you can make to quit chewing and remaining a non-chewer

1. **What will you do to make betel quid unavailable to you?**
   a. _____
   b. _____
   c. _____

2. **What will you do to increase time spent in non-chewing areas or doing non-chewing activities?**
   a. _____
   b. _____
   c. _____

3. **How can you get help from others while trying to quit?**
   a. _____
   b. _____
   c. _____

4. **What will you do to manage stress successfully?**
   a. _____
   b. _____
   c. _____

5. **What will you do from keep from gaining weight?**
   a. _____
   b. _____
   c. _____

6. **What will you do to be physically active?**
   a. _____
   b. _____
   c. _____

Appendix J –Non BQ Chewing Game Plan : Coping with High Risk Situation

Worksheet

NON-BQ CHEWING GAME PLAN COPING WITH HIGH-RISK SITUATION WORKSHEET

High-Risk Situations (Week of: 1 / 2 / 3 / 4)

For each specific high-risk situation, describe the event, persons you might be with, what you might be doing, thinking, or feeling at the time.

List the specific coping strategies you will use to avoid chewing in each case.

Remember 3As: Avoid, Alter, use Alternatives

NO.	HIGH-RISK SITUATIONS	SPECIFIC COPING STRATEGIES
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

Appendix K - Social Support for Non- BQ Chewing Worksheet

SOCIAL SUPPORT FOR NON-BQ CHEWING WORKSHEET

Getting support and encouragement from others while you quit and work at being a non-chewer can be very helpful. Complete this handout to help you determine what other people do that is helpful or not helpful to you and what you can do to ask them to be more helpful.

Supportive Behaviors for Nonchewing:

List behaviors from others that you consider to be helpful or supportive to your nonchewing efforts:

1. _____
2. _____
3. _____

Supportive Behaviors for Nonchewing:

List behaviors from others that you consider to be not helpful or that interfere with your efforts to quit chewing:

1. _____
2. _____
3. _____

Requesting Behavior Change from Others:

What can you ask or request from others to have them engage in more actions or behaviours that you find supportive of nonchewing?

1. _____
2. _____
3. _____

What can you ask or request from others to have them engage in fewer (or eliminate completely) behaviors that you find not helpful or interfere with your efforts to quit chewing?

1. _____
2. _____
3. _____

Appendix L -Positive and Negative Thoughts Worksheet

POSITIVE AND NEGATIVE THOUGHTS WORKSHEET

INSTRUCTIONS: For the next week, keep track of your positive and negative thoughts. Remember, you don't need to write down every thought, just the ones that send you clear positive or negative messages.

POSITIVE THOUGHTS	NEGATIVE THOUGHTS

WRITE DOWN A TECHNIQUE YOU CAN USE TO INCREASE POSITIVE THOUGHTS	WRITE DOWN A TECHNIQUE YOU CAN USE TO REDUCE NEGATIVE THOUGHTS

HOW EFFECTIVE IT WAS FOR YOU?				
1	2	3	4	5
Not Effective				Very Effective

HOW EFFECTIVE IT WAS FOR YOU?				
1	2	3	4	5
Not Effective				Very Effective

Appendix M - Follow-Up Questionnaires

ID

JABATAN KESIHATAN PERGIGIAN MASYARAKAT DAN PENCEGAHAN KLINIKAL

Cross-Cultural Adaptation of a Betel Quid Cessation Program and Evaluation of Its Effectiveness in A Malaysian High-Risk Community

Dr. Mary Melissa A/P Sarimuthu, Professor Dr. Jennifer Geraldine Doss,
Associate Prof. Dr. Amer Siddiq Bin Amer Nordin

FOLLOW-UP QUESTIONNAIRE

Office use

***Date of Program*:** _____

Name (*as in Identity Card*)**:** _____

Address *(current home address)*: _____

_____

***Telephone No.*:** _____

No. Intervention Session Attended.: _____

Reasons for Absence (if any): _____

1. What is your current betel quid chewing status? ☐ ***B1***
   d. No such habit (proceed to xx)
   e. Habit currently practiced
   f. Past-habit and now has stopped

2. For current chewer, how often do you chew betel quid now? ☐ ***B2***
   a. Daily
   b. 2-3 times a week
   c. Few times a month
   d. I am an occasional betel quid chewer
   e. Others, please specify: _____

3. How many quid(s) do you chew in a day? ☐☐ ☐ ***B3***

4. What is (are) the ingredients that you use in your betel quid? ☐ ***B4***
   a. Areca nut
   b. Tobacco
   c. Betel leaf
   d. Lime
   e. Gambir
   f. Others
   (If yes, please specify: _____)

The End