EFFICACY OF GROUP TOBACCO CESSATION BEHAVIOURAL INTERVENTION AMONG TOBACCO USERS WITH CONCOMITANT MENTAL ILLNESS IN KENYA

A PHD THESIS SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE AWARD OF DOCTOR OF PHILOSOPHY IN CLINICAL PSYCHOLOGY OF THE UNIVERSITY OF NAIROBI

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Dedication

To God almighty for His grace and mercies over my life.

To my supportive family: My mum, Millicent Oduor, son, Terence Olando, Brothers- Brian ochieng, Neil Omondi, Leslie Otieno, Bonface Onyango; thank you so much.

To those who are struggling to quit tobacco use; keep keeping on, you will succeed it as long as you don’t stop trying.

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List of abbreviations

APA	American Psychiatric Association
AOD	Alcohol and Other Drugs
CBT	Cognitive Behavioural Therapy
CDC	Centers for Disease Control and Prevention
CSAT	Clinic for Substance Abuse Treatment
DALYs	Disability-Adjusted Life years
DSM	Diagnostic and Statistical Manual of Mental Disorders
ICD	International Classification of Diseases
NACOSTI	National Commission for Science, Technology and Innovation
NRT	Nicotine Replacement Therapy
NSDUH	National Survey on Drug Use and Health
SPSS	Statistical Package for Social Sciences
UON	University of Nairobi
WHO	World Health Organization
WHOQOL-BREF	World Health Organization Quality of Life Brief Version
WHO FCTC	World Health Organization Framework Convention Tobacco Control

Abstract

Introduction: The prevalence of tobacco use among people with mental illness is nearly twice that of the general population. Psychotropic medications for tobacco cessation are relatively expensive for most Kenyans. Behavioural counselling and group therapy have been found to be effective, lower cost strategies to promote tobacco cessation, yet have not been studied in Kenya among individuals with concomitant mental illness.

Objectives: Using a randomised clinical trial design, this study sought: 1) to determine the efficacy and safety of a group tobacco cessation behavioural intervention among tobacco using patients with mental illnesses on tobacco cessation at 24 weeks and 2) to evaluate the effect of a group tobacco cessation behavioural intervention on health-related quality of life of patients with mental illnesses at 24 weeks.

Methods: Tobacco users with mental illness who were part of an outpatient mental health program at the Mathari Referral and Teaching Hospital's Clinic for Substance Abuse Treatment (CSAT) and outpatient clinics in Nairobi, Kenya were recruited and allocated into intervention and control groups (1:1). Participants allocated to the intervention group were invited to participate in 1 of 5 tobacco cessation groups. The intervention group received brief counselling based on the 5As (i.e. Ask, Advise, Assess, Assist and Arrange) and assigned to a tobacco cessation group behavioural intervention for 3 months (Meeting fortnightly), which included strategies to manage cravings and withdrawal; stress, anxiety, and coping with depression; assertiveness training and anger management; reasons to quit; benefits of quitting; and different ways of quitting. The intervention group was followed up for 3 months (meeting monthly) after completion of the intervention. Individuals allocated to the control group received usual care. The primary outcome was tobacco cessation at 24 weeks, which was measured through salivary cotinine strips. Secondary outcomes included reduction in tobacco amount used and health-related quality of life at 24 weeks. Between-group event rates of tobacco use were compared between the two groups by unadjusted and adjusted Cox proportional hazard models to evaluate the effect of the intervention on the study outcomes, while differences in HRQoL scores

were analysed using paired t-test. Within-trial qualitative data were also collected using focused group discussions with trial participants to understand their barriers to successful cessation and subsequent facilitators. Data were thematically analyzed. **Results:** Participants' mean age was 35 (SD=9) years, 87% were male, and 42% had completed secondary education. More than half (65%) had substance use disorders (diagnosed), and 15% had major depressive disorder. Almost all participants (94%) used cigarettes at baseline, and participants smoked for a mean of 13 (SD=11) years and a mean of 14 (SD=7) sticks daily. Three-quarters of participants reported using other substances (substance use- not diagnosed). Participants allocated to the intervention group reported a higher cessation rate (15.2% vs 0% at week 12; P=0.02 and 9.1% versus 0%; P=0.10) at week 24, and lower number of sticks smoked (97% vs 58.6%, P<0.0001) compared with control group participants at 24-week follow-up. The unadjusted results showed that participants in the intervention group were almost 14 times more likely to reduce smoking than participants in the control group (97.0% in intervention group vs 58.6% in control group, HR 13.85 [95% CI, 3.95-48.59]). Intervention group participants reported higher health-related quality of life scores in all domains at the end of the study compared with control group participants, including: physical domain (30.6% vs 10.4% OR=3.79 [95% CI, 1.25-11.48]), psychological domain (28.6% vs 16.7% OR=2.19 [95% CI, 0.75-5.33]), social relationships (30.6% vs 16.7% OR=2.21 [95%, 0.83-5.83]), and environmental domain (34.7% vs 8.3% OR=5.84 [95%, 1.79-19.03]). Qualitative results identified themes under *barriers to quitting tobacco use* including: peer influence, withdrawal symptoms, fear of complete cessation, other substance use, and end-month disputes. Themes that were *facilitators* employed by participants to supplement their cessation attempts included: oral stimulation and spousal and friend support.

Conclusion: This group tobacco cessation behavioural intervention among persons with mental illness successfully identified an effective, accessible intervention that improves quality of life in this high-burden outpatient population in Kenya. Future research is needed to evaluate the effectiveness of implementation of this intervention in larger and more diverse populations.

CHAPTER ONE: INTRODUCTION

Background

Mental health is defined as “a state of well-being whereby individuals recognize and realize their abilities, are able to cope with the normal stresses of life, work productively and fruitfully and make a contribution to their communities.”[1] Mental disorders have an impact on individuals and their support systems at large. People with mental disorders suffer more physical, sexual abuse and neglect, and are more prone to suffer degrading treatment practices in health facilities.[2] More than 25% of people globally will suffer from mental, neurological, and substance use disorders at some point during their lifetime.[3] According to the World Health Organization (WHO), about 10% of adult and child populations and at least 20% of all patients seen by general practitioners suffer from some form of mental illness.[3]

According to the Kenya Mental Health Policy (2012-2030), there are no high-quality, representative data on the prevalence of mental health, neurological, and substance use in Kenya. However, this report highlights that about 25% of outpatients and up to 40% of inpatients suffer from mental conditions.[4] Most diagnoses of mental illnesses that are made in general hospital settings are depression, substance use disorders, stress, and anxiety disorders.[5]

People with mental health conditions have been shown to have a vulnerability to tobacco use. Tobacco is a plant grown for its leaves, which are dried and fermented before being put in tobacco products. Tobacco contains nicotine, which is a highly addictive substance. Tobacco contains 7000 of different chemicals where 69 are carcinogenic. There are different modes of consuming tobacco, including; smoking, chewing, sniffing, and rubbing on gums. Smoked tobacco products include cigarettes, cigars, bidis, roll-your-own, loose tobacco in pipes, shisha (hookah) and

kreteks. Chewed tobacco products include chewing tobacco, snuff, dip, and snus; snuff can also be sniffed. [6]

Nicotine is a highly addictive chemical contained in tobacco that is quickly absorbed into the bloodstream. Nicotine stimulates the neuro-transmitter dopamine, which is associated with pleasurable feelings.[7] Tobacco users quickly develop regular tobacco use patterns, which ensure release of a steady stream of dopamine. When the nicotine content in their blood drops below a certain level, tobacco users begin to crave tobacco use. This craving causes a feeling of “stress” until the craving is relieved. The relief felt when this craving is finally satisfied is the feeling that tobacco users commonly mistake as “relaxing”. Eventually, tobacco users need increasing levels of nicotine to feel “normal”.[8]

For tobacco users with a mental illness, the association between tobacco use and feeling relaxed is more pronounced.[9] It is commonly believed that people with a mental illness use tobacco to self-medicate.[10] Other possible explanations for the particularly high rates of tobacco use amongst the mentally ill include a possible common genetic vulnerability,[11] a greater susceptibility to addiction because of a greater subjective experience of reward or pleasure, wherein tobacco may relieve some symptoms related to behavioural disorders, or less susceptibility to anti-tobacco use messages. Another possible explanation for continuing to use tobacco is relatively more intense withdrawal symptoms.[12]

Nicotine dependence is similar to that of alcohol, heroin, and cocaine.[13] It can produce compulsive and obsessive patterns of substance use; it is positively and negatively reinforcing; its use occurs despite acknowledged harmful effects; craving and relapse follow brief abstinence; and it produces both tolerance and physical dependence as indicated by withdrawal signs and symptoms.[13]

Negative health effects of tobacco use have been well documented.[14] Complications can also be due to second-hand smoke, which cause more than 600,000 deaths globally per year, with over 80% of these deaths occurring in low- and middle-income countries.[15] Nicotine effects on the brain, particularly in new smokers include: dizziness, light-headedness, and sometimes vertigo.[16] These effects can also be elicited in chronic smokers with forced rapid smoking. Smokers learn to avoid such effects by gaining “fingertip control” of blood levels by adjusting their inhalation patterns.[16]

In Kenya, non-communicable, chronic diseases contribute over 50% of all hospital admissions, causing over 30% of total in-hospital mortality.[17] Reports in Kenya show that 69 per 100,000 deaths among individuals aged 30 years and older are as a result of tobacco use, and 20% of all non-communicable, chronic disease-related deaths result from tobacco use.[18] Maina and Nato (2009) highlighted that treating diseases caused by consumption of tobacco use in Kenya was expensive, contributing to 6% to 15% of the total health care cost by government.[19]

The impact of tobacco use has been identified above; and as such, it is important to address barriers to tobacco cessation that might affect most tobacco users making a quit attempt. A 2014 systematic review of the qualitative and quantitative literature on perceived barriers to smoking cessation in selected vulnerable groups identified withdrawal from nicotine as a challenge to mental well-being, as well as barriers of increased stress, weight gain, fear of failure, and boredom.[20, 21, 22]

Behavioural strategies have been shown to help manage most of the barriers to tobacco cessation. These strategies help tobacco users’ gain practical experience

to develop and practice facilitators for managing mood, coping with stress, dealing with cravings, and maintaining successful cessation efforts.[23]

To support cessation attempts and successful quits, identifying immediate and long-term benefits could provide the needed motivation. Education about these benefits can be a useful motivational tool. Positive health changes occur almost immediately after patients stop tobacco use. For example, blood pressure and pulse rate return to normal approximately 20 minutes after stopping tobacco use. About 8 hours later, nicotine and carbon monoxide levels in the bloodstream reduce by half, and oxygen levels return to normal. In 24 hours, carbon monoxide is eliminated from the body. The lungs start to clear out mucus and other smoking debris. Forty-eight hours later, there is generally no nicotine left in the body. The ability to taste and smell improves. Three days later, breathing becomes easier, bronchial tubes begin to relax, and energy levels increase. Quitting smoking immediately reduces risks for cardiovascular disease and cancer, including cancers of the esophagus, larynx, kidney, pancreas, and cervix.[24] Other general benefits include improved general health, improved taste and smell, and improvement in physical activity.

There have been misconceptions that people with mental illness generally have lower quit rates compared to the general population. These have been disproven as research has shown that individuals with mental illness can achieve similar quit rates to individuals without mental illness with access to appropriate cessation services.[25] Morris et al.,(2009) found that most mental health providers receive little or no training on smoking cessation and frequently have misconceptions about tobacco use in this population, such as that patients with mental illnesses need to use tobacco to control their psychiatric symptoms and that these individuals have no desire to quit.[26] A 2013 Cochrane systematic review demonstrated how

myths have led to persistently high tobacco use among the mentally ill, including myths that persons suffering psychological disorders lack motivation for tobacco cessation, that individuals with mental illness do not have the capacity to quit, and that efforts to quit may actually impede their mental health treatment.[27] Because of this misinformation, lack of awareness, and limited competency in implementing smoking cessation interventions among mental health care workers, tobacco use among this special group has been overlooked, depriving mental health patients of the necessary interventions for its control.[28]

Studies have consistently found that tobacco cessation is associated with reduced depression, anxiety, and stress, as well as improved quality of life.[29] As such, both the United States' Centers for Disease Control and Prevention (CDC) and American Psychiatric Association (APA) encourage integration of cessation treatment with mental health services.[30]

Statement of the problem

Nicotine dependence is recognized as a mental and behavioural disorder in the International Classification of Diseases (ICD-11) of the World Health Organization (WHO)[31] and as Tobacco use disorder in the 5th Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatry Association (DSM-V).[32] Patients with serious mental disorders have a greater prevalence of tobacco use,[33] more severe psychiatric symptoms, poorer overall general well-being, and greater functional impairment when compared to non-tobacco users.[34] They smoke at 2 to 4 times the rate of the general population.[35]

Tobacco-related illnesses including cancer, heart disease, and lung disease are among the most common causes of death among persons with mental illness.

There is a stepwise, dose-response relationship between amount of smoking or smoke exposure and excess mortality.[36]

Tobacco use affects the metabolism of various medications, including diazepam, haloperidol (partial), olanzapine (partial), clozapine, mirtazapine (partial), tricyclic antidepressants, barbiturates, and benzodiazepines. Tobacco cessation may improve the effectiveness of medication and reduce the amount needed. There are polycyclic aromatic hydrocarbons (PAH) within tobacco smoke that increase the activity of certain hepatic enzymes (CYP1A2, in particular).[37] For some drugs used in psychiatry, smoking significantly reduces drug plasma levels, and higher doses of psychotropic medications are required than in non-smokers. When smokers quit, enzyme activity reduces over approximately 1 week, and nicotine replacement appears to have no effect on this process. Plasma levels of affected drugs will then rise, sometimes substantially. Dose reductions will usually be necessary. If smoking is restarted, then enzyme activity increases, plasma levels fall, and dose increases are therefore required. This highlights the importance of smoking cessation among this population, particularly in low- and middle-income countries (LMICs), where affording the psychotropic medications might be problematic for many patients due to out-of-pocket costs.

For effective tobacco cessation, healthcare providers attending to this population should be able to provide evidence-based cessation interventions. However, according to Ratschen et al., (2011) both patients and healthcare providers have limited knowledge and practice on how to treat tobacco dependence, although affordable and effective treatments for nicotine dependence exist.[38]

To address some of the issues identified, the study will seek to answer the following research questions/objectives.

Research Questions

1. What impact has group tobacco cessation behavioural intervention on smoking reduction and successful quits?
2. What are the health-related quality of life effects of tobacco cessation?
3. What are the barriers to successful tobacco cessation while undergoing group tobacco cessation behavioural intervention?
4. What are some facilitators adapted by individuals to support their cessation attempts?

General Study Objectives

To evaluate the effect of a group tobacco cessation behavioural intervention on successful cessation and improvement in HRQoL among tobacco using patients with concomitant mental illnesses at 24 weeks.

Specific Study Objectives

1. To evaluate the impact of group tobacco cessation behavioural intervention on smoking reduction and successful quits.
2. To examine the association between changes in tobacco use and changes in HRQoL among the patients.
3. To identify the barriers to successful tobacco cessations.
4. To find out facilitators used by patients in their quit attempts.

Justification for a Tobacco Cessation Program among Patients with Mental Illness

Some mental health professionals have reported that people with mental health issues are not motivated to quit tobacco use.[39, 40] However, a 2014 *BMJ* systematic review and meta-analysis noted that:

"*There is consistent evidence that stopping smoking is associated with improvements in depression, anxiety, stress, psychological quality of life, and positive affect compared with continuing to smoke. The strength of association is similar for both the general population and clinical populations, including those with mental health disorders".*[41]

Tobacco cessation interventions, whether brief interventions, intensive individual or group support, or pharmacotherapies, are among the most cost-effective interventions available in reducing morbidity and mortality, even if an individual has used tobacco for many years.

Although brief tobacco cessation interventions are widely recommended in medical settings, [42] such interventions have rarely been implemented or studied in mental health settings in Kenya. In fact, only 3 out of every 10 smokers who visited a healthcare provider in the past 12 months in Kenya were asked about tobacco use status or advised to quit smoking.[43] Moreover, there is only 1 tobacco cessation clinic (dental school) in Kenya with very few trained tobacco cessation professionals to serve the whole country; and of those trained, none are based in any mental health care settings. This is despite the clinician detection rate of mental disorders prevalence in Kenya to be 4.1% of the adult population.[44] Tobacco cessation services that exist are not tailored to meet the intensity of services required by persons with mental illnesses.[45] Tobacco users with mental illness are frequently motivated to quit and are generally able to do so provided they are given evidence-based support. While aided quit rates for persons with mental illnesses are lower than for general populations, their quit rates are still substantial. Studies have found

individuals with history of major depression have quit rates as high as 38%, while for schizophrenia quit rates may be between 10% and 30%.[46]

This study focused on 5As and group behavioural intervention because this approach is more practical in this setting as opposed to combined intervention of behavioural and pharmacotherapies. This approach is also more accessible because most Kenyan patients with mental illness find it difficult to afford their regular psychotropic medications, [47, 48] let alone the tobacco cessation pharmacotherapies.

Few studies have focused on group behavioural interventions without addition of pharmacotherapies among this group, and few if any, of these studies in Africa. In Kenya, where this study was based, there is limited access to tobacco cessation pharmacotherapies and those that are available are not affordable to most of this population. As a result, the current study focused on evaluating the effect of an accessible, evidence-based tobacco cessation intervention among patients with mentally illness attending the Centre for Substance Abuse Treatment (CSAT) outpatient program at Mathari Teaching and Referral Hospital.

There has been no purposive focus on tobacco cessation among individuals with mental illness in Kenya, which represents an important knowledge gap that this study aims to fill.

CHAPTER TWO: LITERATURE REVIEW

Global Trends in Tobacco use

Tobacco use has been called an epidemic by the World Health Organization (WHO), as it kills more than 8 million people a year around the world. More than 7 million deaths are the result of direct tobacco use, while around 1.2 million are the result of non-smokers being exposed to second-hand smoke.[49] In 2011, tobacco use killed more than 6 million people, nearly 80% in LMICs. Between 2002 and 2030, tobacco attributable deaths are projected to decline by 9% in high-income countries, but are expected to double from 3.4 million to 6.8 million in LMICs.[49] Almost every seventh death in the world (13%) resulted from direct smoking in 2017, and a further 2% was the result of second-hand smoke. This means 15% – close to 1 out of every 6 deaths was caused by tobacco.[49, 50]

One in every 5 adults (20%) aged 15 years and older in the world smoke tobacco. Countries with some of the highest prevalence of tobacco use include; Kiribati (47%), Montenegro (46%), Greece (43%), Timor (43%), and Nauru (40%), with males (35%) having substantially higher tobacco use rates than women (6%) around the world.[50] However, very few people smoke in some countries: for example, in Ethiopia, Ghana, Peru and Honduras, less than 5% smoke.

Prevalence of Tobacco Use in Africa

In Sub-Saharan Africa, the patterns of tobacco consumption vary widely, both between and within countries. Despite this variation, the prevalence of tobacco use, as well as the amounts consumed are higher among men, irrespective of age and ethnicity.[51] Among men, the highest prevalence of tobacco consumption was observed among coloured males in South Africa (79%), and the lowest in Nigeria undergraduate students (9%). In women, the highest prevalence was recorded

among Luo Kenyans (67%) and the lowest among Nigerian general medical patients (0.3%).[52]

The prevalence of consumption of smokeless tobacco and hand-rolled cigarettes is highest in Lesotho, Madagascar, Mozambique, Namibia and Zambia- ranging from 10.4% to 24.1% and lowest (below 2%) in Ghana, Nigeria, Ethiopia, Kenya, Zimbabwe, and Tanzania.[52]

Sub-Saharan Africa appears to differ from other regions of the world in having reached only the early stages of the cigarette epidemic. Estimates suggest that deaths from smoking-attributed causes reach only 5–7% for men and 1–2% for women.[53]

Prevalence of Tobacco Use in Kenya

Kenya has the highest recorded smoking prevalence in Sub-Saharan Africa.[54] Kenya has however made steps in its tobacco control efforts, leading to reduction in prevalence. By 2017, Euromonitor International estimated that the total smoking population had reached 3 million (2.7 million men and 1.3 million women), and while overall smoking prevalence had fallen slightly from 11.6% in 2014 to 11% in 2017, the total number of smokers in the country continues to rise.[54]

The Global Adults Tobacco Survey-Kenya (GATS) of 2014, showed that approximately 2.5 million adults in Kenya (11.6% of the adult population) used tobacco products with higher rates among men (19.1%) compared with women (4.5%).[55] Smokeless tobacco use prevalence in Kenya was 4.5% overall (1.1 million), with less pronounced sex differences (5.3% among men and 3.8% among women) than other forms of tobacco use.

The Kenya Global Youth Tobacco Survey (GYTS) of 2013 showed that 9.9% of school going children aged 13-15 years were using tobacco products with higher

rates among boys (12.8%) compared with girls (6.7%).[56] The survey showed that 4.9% smoked cigarettes, while 3.9% used smokeless tobacco. Surprisingly, the highest prevalence rates have been shown among students in medical/health sciences schools. The Kenya Global Health Professional Students survey (GHPSS) of 2009 found that 9.8% of medical students, 47.8% of dental students, 60.5% of pharmacy students, and 34.9% of nursing students currently smoked cigarettes.

Among adults who used tobacco according to the GATS-Kenya 2014 survey, 52.4% attempted to quit smoking in the past 12 months. Among those who attempted to quit, 70% tried to quit without any assistance. While those who visited a healthcare provider in the past 12 months, 30% were advised to quit smoking. The survey also showed that 77.4% of current smokers planned to or were thinking about quitting, which is similar to the worldwide report that shows that approximately 70% of smokers report that they want to quit.[57] Tobacco users trying to quit need supportive therapy from trained professionals.

It is estimated that 60% of patients treated in health facilities in tobacco growing areas suffer from tobacco related ailments.[58] In Kenya, 69 per 100,000 deaths for individuals aged 30 years and above are as a result of tobacco use. Approximately 1 out of every 5 (20.3%) deaths due to non-communicable, chronic diseases is caused by tobacco use, and 55% of all deaths from cancers of the trachea, bronchitis, and lung are attributable to tobacco.[59]

Prevalence of Tobacco Use among Persons with Concomitant Mental Illness

Globally, an estimated 264 million people are affected by depression, with women being more affected than men. Worldwide, bipolar disorder affects about 45 million people, schizophrenia affects 20 million people, and dementia affects approximately 50 million people.[60]

In Sub-Saharan Africa, rates of psychological disorders in adults are particularly elevated, with rates of posttraumatic stress disorder, anxiety, and depression ranging from 20% to 60%.[61] In a study in Ethiopia, exploring the prevalence of tobacco use among persons with mental illness, tobacco dependence was more prevalent among participants who chewed khat daily at 39%, with bipolar disorder at 16.9%, and schizophrenia was 29.1%. However, among participants with major depressive disorder, tobacco use was 8.6%. The prevalence of tobacco dependence among participants who had a co-morbid medical illness was 17.9%.[62]

In Kenya, mental illness is common, with prevalence rates of 4% for major mental disorders, which is comparable with the prevalence rates reported in high-income countries.[44] Alcohol has been shown to be associated with increased tobacco use in sub-populations such as rural Kenya and Nairobi slums.[63]

Smoking is 2 to 3 times more prevalent among people with mental illness, when compared with the general population as reported in the United States, United Kingdom, and Australia.[64] Smoking prevalence is particularly high (almost 5-fold greater) among those with schizophrenia, bipolar disorder, post-traumatic stress disorder (PTSD), and alcohol/illicit drug use disorders. Smoking prevalence increases with a greater number of mental disorders, ranging from 18% for people with no mental illness to 61% for people diagnosed with 3 or more mental disorders.[65]

In the United States, smokers with mental illness account for more than 200,000 of the 520,000 tobacco-attributable deaths annually and are dying on average 25 years prematurely, with leading causes being chronic disease, most of which are tobacco related. Comparable estimates in years of life lost have been reported in Australia, New Zealand, and Canada.[64]

The association between mental illness and tobacco use has further been demonstrated by other studies conducted in the United States. Data from the 2012-2014 National Survey on Drug Use and Health (NSDUH) in the United States found that 33% of adults with any mental illness were current (past month) smokers, compared to 21% of adults without any mental illness.[66] Almost 3 out of every 10 smokers (30%) had mental illness, nearly half of adults with mental illness below the poverty line were current smokers, and people with mental illness tended to be heavier smokers.[30,67] According to NSDUH, nearly one-third (31%) of cigarettes smoked by adults were smoked by those with mental illness.[66] The recent decades have been characterized by an increasing in 'Stop smoking' campaigns and restrictions in the access of cigarettes as well as introductions of smoking zones in most parts of the world. Although data from NSDUH also show that, from 2008 to 2016, there was a slower decline in smoking rates among those with serious psychological distress, it still remained twice as high compared with those without serious psychological distress.[68]

Effects of Tobacco Use on People with Mental Illness

Tobacco use contributes significantly to the main causes of morbidity and mortality in people with mental health disorders. Half of all long-term smokers will die of a smoking related illness.[69] Long-time tobacco use has been shown to trigger and exacerbate mental illness. It also results in poorer treatment outcomes and increased hospital admissions compared to the general populations.[70, 71]

As a consequence of tobacco use, individuals with a mental illness are more likely to have a chronic disease and to have a shorter life expectancy.[72, 73] Tobacco-related illnesses including cancer, heart disease, and lung disease are among the

most common causes of death among the mentally ill. Individuals with serious mental illness and substance abuse treated in the public health system die a startling 25 years earlier than those without mental illness.[74]

An 11-year retrospective study that followed up on individuals who received addiction treatment found that more than half of all deaths were tobacco-related.[75] While in a 24-year prospective study of heroin users entering treatment, the death rate of smokers was found to be 4 times that of non-smokers, making smoking status a significant predictor for death in this population.[76]

Tobacco Cessation Interventions among Users with Mental Illness

The WHO guidelines state there is no suggestion of inconsistency between the evidence for tobacco-cessation interventions in the general population and in people with severe mental health conditions, and while pharmacological smoking-cessation interventions in general can be considered safe, clinicians should be cautious of drug interactions with other psychotropic medication.[77]

Hospitals have been recognised as a key setting for initiating the delivery of tobacco cessation care.[78, 79] However, as is the case in general medical settings, evidence from psychiatric settings suggests that without post-discharge support, tobacco use is likely to return to pre-admission levels within 2 weeks.[80] Such findings suggest a need for adequate and consistent support to encourage a sustained quit attempt and prevent relapse. Multimodal post-discharge cessation support of at least 4 weeks in length or greater can result in higher rates of successful smoking cessation according to a systematic review evidence from general medical settings.[80]

Specialised smoking cessation, cognitive behavioural therapy- (CBT) based interventions have been shown to be efficacious in tobacco users with concomitant

mental illness. A manual-based programme of 4-8 weeks CBT tailored for people with mental illness was effective in achieving a 16% quit rate at the end of treatment and 19% quit rate at one-year follow-up in an uncontrolled sample of people with "severe and persistent" mental illness in the community. Quit rates were comparable to the general population. Notably, 14 of 15 quitters were also taking NRT to support their quitting. Similarly, veterans with mental health diagnoses enrolled in the Mental Health Clinical Smoking Cessation Programme, which included 6 weeks of group counselling, bupropion, nicotine replacement therapy (NRT), or a combination thereof demonstrated a 36% quit rate at the end of treatment.[81] A limitation noted in these studies is that the sample sizes are very small and located in high-income country settings, the latter is a gap that this study aimed to address given that the study was set in a low income country.

The 5As Approach to Cessation

The 5As (Ask, Advice, Assess, Assist and Arrange) brief intervention approach has been implemented around the world.[82,83] It serves a guideline for primary care health providers who are not specialists in tobacco cessation to provide routine tobacco cessation intervention in their daily practices.[84]

Effective strategies that can be used with those with serious mental illness are contingent reinforcement,[85] motivational interviewing, the 5A's (Ask, Advise, Assess, Assist, Arrange), and for those who have low motivation, then the 5 R's (Relevance, Risks, Rewards, Roadblocks, Repetition) are introduced to try to motivate them.[86]

Nicotine Replacement Therapy

Six different forms of NRT are available for use as tobacco cessation aids: nicotine patch, gum, lozenge, inhaler, nasal spray, and sublingual tablet (micro tab). These provide a “clean” alternative source of nicotine without the other 7000 toxic chemicals found in tobacco smoke. All deliver a lower dose of nicotine than would be received through conventional tobacco use with the primary difference being differing absorption rates as a result of different methods of delivery.

Combining NRT with non-NRT pharmacotherapy has been shown to increase efficacy of either therapy alone in tobacco users with co-morbid mental illness.[87,88] Randomized trials have shown that tobacco cessation treatment among patients receiving concomitant mental health treatment is effective and safe, does not exacerbate mental health symptoms, and does not lead to increased use of alcohol or illicit drugs.[38] Most treatment studies involved using inpatient participants and more than one type of therapy in participants with or without mental illness (e.g., CBT plus bupropion vs. NRT).[89]

Group programs have the advantage of multiple meetings and coping strategy exchange.[90] Liberman and Bedell highlight that behavioural methods are employed to: 1) reduce the reintroducing value of smoking, 2) create an aversion for smoking, 3) develop self-monitoring of smoking behaviour, and 4) establish competing coping responses.[91] They also suggest that smokers will quit more successfully if they have fewer smokers as friends. Analyses of prior relapse, tracking of smoking needs, and focusing on reasons for quitting are components of many therapeutic approaches. A key element to successful cessation includes learning and appropriate use of coping skills to prevent relapse.[92, 93]

Quitting could potentially allow patients to take lower doses of psychiatric medicine while getting the same treatment results. For that reason, smokers with mental illness often need to take higher doses of their medicine to get the same effect as another patient who does not smoke.[94]

Cochrane systematic reviews highlight that the tobacco cessation interventions listed above, including medications used as tobacco cessation aids, are helpful in helping smokers reduce their tobacco intake and quit smoking.[95, 96] The reviews identified 132 trials, and 111 trials with >40,000 participants contributed to the primary comparison between any type of NRT and a placebo or non-NRT control group on the outcome of tobacco cessation. The relative rate (RR) of abstinence for any form of NRT relative to control was 1.58 (95% confidence interval [CI]: 1.50 to 1.66). The pooled RRs for each type were 1.43 (95% CI: 1.33 -1.53, 53 trials) for nicotine gum; 1.66 (95% CI: 1.53 - 1.81, 41 trials) for nicotine patch; 1.90 (95% CI: 1.36 - 2.67, 4 trials) for nicotine inhaler; 2.00 (95% CI: 1.63 - 2.45, 6 trials) for oral tablets/lozenges; and 2.02 (95% CI: 1.49 - 3.73, 4 trials) for nicotine nasal spray. The effects were largely independent of the duration of therapy, the intensity of additional support provided, or the setting in which the NRT was offered. The effect was similar in a small group of studies that aimed to assess use of NRT obtained without a prescription. The effectiveness of NRT appears to be largely independent of the intensity of additional support provided to the individual. However, none of these studies focused on participants with mental health issues.

Tobacco Use and Quality of Life

Health-related quality of life (HRQoL) can be seen as satisfaction with ones' well-being particularly improvement of ones' physical, social, family, or psychological

health.[97] Studies indicate that among patients with mental illness, HRQoL is an indicator of the quality of care they receive.[98] Most stable patients with mental illness can give a reliable assessment of their quality of life, and most were dissatisfied with life circumstances. In places of doubt, relatives' additional input is warranted.[99]

There are few studies that explore the relationship between smoking and HRQoL in the general population. These studies' messages appear to be consistent across all studies; and that is, smokers are likely to have worse HRQoL. Smoking is significantly and negatively associated with HRQoL in English general population, and the magnitude of this association is determined by the number of cigarettes smoked.[100]

A study on impact of smoking on HRQoL in West Iran found that the highest proportion of self-reported problems (including both 'some' and 'severe') were related to current, heavy smokers, with high nicotine dependence. Regression analysis indicated that current smokers had a significantly lower HRQoL compared to past smokers and never smokers ($p < 0.05$). Heavy smokers also had a significantly lower HRQoL score than moderate and light smokers ($p < 0.05$) and there was an inverse relationship between the HRQoL score and nicotine dependence ($p<0.05$). The current smokers, heavy smokers, and high nicotine dependent smokers had lower HRQoL scores. These findings provide inputs for better understanding and for devising interventions for smoking cessation, reducing the number of cigarettes smoked per day and nicotine dependency.[101]

Goldenberg et al.,(2014) found that low HRQoL and depression are associated with higher odds of smoking initiation and lower odds of successful smoking cessation. There is a negative relationship between smoking and HRQoL and the magnitude of this association is related to the number of cigarettes smoked.

Second-hand smoke also appears to be negatively associated with HRQoL. Smoking cessation significantly improves HRQoL.[102]

Behavioural Support for Tobacco Cessation

Group therapy offers the added value of fostering peer support and is likely to be more cost-effective than individual counselling, though few head-to-head comparisons have been conducted. Brief counselling with motivational interviewing strategies is also effective.[103]

Evidence from 2 randomized controlled trials supports greater effectiveness of motivational interviewing, compared with simply providing brief advice to quit smoking if time is available. Motivational interviewing is defined as a direct, patient-centred counselling intervention guided by 4 general principles: 1) expressing empathy, 2) developing discrepancy to help smokers appreciate the value of change by exploring the discrepancy between how they want their lives to be versus how they are currently, 3) rolling with resistance, and 4) supporting self-efficacy.[104]

More intensive support has been found to be more effective and can be delivered by treatment specialists. Such support may include intensive counselling, culture-specific counselling, visits to more than one consulting physician, intra-treatment social support, group counselling sessions, and other areas of support that are beyond what a single clinician may be able to offer.[103]

Thirteen trials compared a group program with a self-help program, and overall, data demonstrate a higher rate of cessation with the use of a group program (RR = 1.98, 95% CI 1.60 to 2.46). There is some evidence to suggest that group support may be more effective than one-to-one support and should involve multiple sessions.[104] Intensive behavioural support had a higher odds of tobacco cessation when compared with brief advice (ORs = 1.56 [95% CI, 1.32-1.84]), and group

support had an even larger effect (OR = 2.04 [95% CI, 1.60-2.60]). There is also evidence that such behavioural sessions can be effective even if conducted over the telephone when compared with brief advice (OR = 1.64, 95% CI 1.41 to 1.92).[105] Group therapy has been found to be better for helping people stop tobacco use than self-help, and other less intensive interventions.[106]

In the Cochrane review database on tobacco cessation group therapy, none of the studies reviewed focused on patients with mental illness, and few, if any, were performed in LMICs. This proposed study will therefore provide knowledge on how these therapy groups work with this population.

Theoretical Framework for Behavior Change Model

The trans-theoretical model or stage of change model was developed by Prochaska and DiClemente in 1982. The model emphasizes that the behavioural change consists of 5 stages (pre-contemplation, contemplation, preparation, action, and maintenance), and individuals need special applications of these stages to be successful.[107] The model not only emphasizes that individuals are in different stages of behavioural change but also states that when all individuals are given the same information, there is a risk of developing resistance against change.[108] The model is effective in tobacco cessation studies.[109,110]

Using the trans-theoretical model, once tobacco users are identified, it is essential to determine their level of readiness to quit. Failure to do so is one of the major reasons that interventions are unsuccessful.[111]

Pre-contemplation

Individuals in the pre-contemplation stage have not planned to make a quit attempt. The W.H.O toolkit for delivering the 5As and 5Rs brief interventions in primary care recommends that it is important to ask about tobacco use and advise tobacco users to quit at each clinic visit.[112] Effectiveness of interventions may be increased if the health risks of tobacco use can be personalized or if existing health problems can be linked to tobacco use.[113]

Contemplation

In this stage of contemplation, tobacco users are seriously considering a cessation attempt. Assessment of other individualized or environmental factors suspected of affecting cessation outcome, such as severity of withdrawal symptoms, depression, stress, or presence of other smokers in the home, may be carried out. A statement of intent to quit tobacco use has been shown to be a powerful predictor of positive change in future tobacco quit attempt .[114]

Preparation

The degree of commitment, motivation, and confidence that the individual brings to the cessation effort significantly impacts the outcome.[115] Essential points to address at this stage include: symptoms of nicotine withdrawal, strategies for attenuating those symptoms, options for pharmacological interventions, and personal concerns related to quitting. Symptoms of nicotine withdrawal are usually most intense and debilitating during the first week following tobacco cessation and last an average of 3 weeks.[116] However, the craving for nicotine may last longer, sometimes recurring months later, or even longer.[117]

Action

In this stage, tobacco users attempt to quit by implementing the cessation plan developed during the preparation phase. Changing daily routines and engaging in activities that makes tobacco use difficult such as exercise, washing a car, or keeping one's hands busy with activities as writing/knitting can be effective in diverting attention from nicotine withdrawal symptoms and craving.[118]

During follow-up appointments, tobacco use status should be assessed, progress and problems discussed, facilitators reviewed, and the importance of total abstinence emphasized.

Maintenance

People in the maintenance stage have been abstinent for more than 6 months and are attempting to remain so. Intermittent follow up appointments are needed to focus on tobacco cessation for 2 reasons:

1. Such visits increase abstinence rates and reduce the rate of relapses.
2. Tobacco use is a chronic problem, and patients with chronic problems should be seen on a regular basis.

During these visits, progress can be evaluated, congratulations can be offered when appropriate, reinforcement of the decision to quit, and encouragement to remain abstinent be provided. Those who fail to show for follow-up visits should be contacted to maintain continuity of care.[119]

Relapse

Relapse or resumption of regular tobacco use can occur anytime during the cessation process. Most relapses occur during the first 2 weeks of tobacco cessation. Techniques to prevent relapse include continuing to identify tobacco use

triggers and coping skills to use when they are encountered because those with a greater number and variety of responses are more likely to remain abstinent. Relapse should be considered a learning experience and evidence of determination to quit rather than failure.[120] The circumstances of relapse should be identified and strategies to avoid these situations identified.

Conceptual Framework

This conceptual framework is based on the trans-theoretical model, which posits that people have different levels of motivation to change, are in different stages of change, need motivation during decisional balancing, and need support to develop self-efficacy.[107] The target population for the current study are patients with well managed (stable) mental illness and who use tobacco products.

As an integrative model, the trans-theoretical model stages of change assume tobacco users go through stages to quit successfully.

1. Not at all thinking about quitting (Pre-contemplation)
2. Thinking about quitting (Contemplation)
3. Making preparations to quit (Preparations)
4. Taking action to quit (Action)
5. Quitting and remaining tobacco free (maintenance)

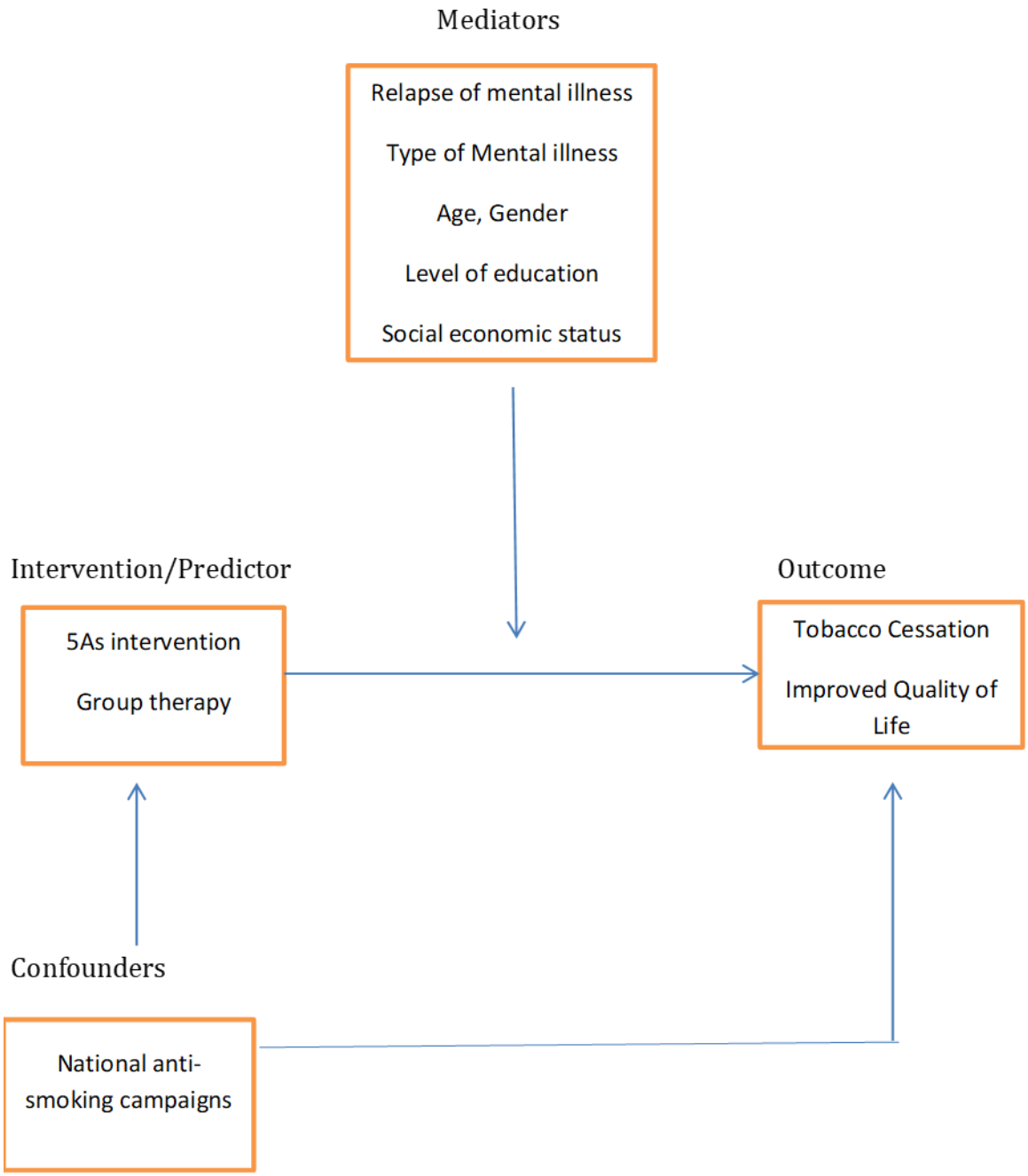
Different mediators can affect the stage of change, and particularly the speed of change. In this study, some moderators include: 1) type of mental illness and relapse of mental illness, as these may worsen cravings for tobacco use; 2) age and gender, as these have been shown to affect the amount used; and 3) level of

education and socio-economic position because mental illness and tobacco use are related to these factors.[121,122,123]

The initiating session in the current study used the 5As brief session, while the main intervention was group tobacco cessation behavioural therapy (combined motivational interviewing and CBT) as independent variables, while the outcomes (tobacco use reduction, tobacco cessation, and improvement of HRQoL) were dependent variables.

At the beginning of the study, important, potential attenuating factor was the presence of national anti-smoking mass media campaigns, which are held annually during World No Tobacco Day on 31st May. This and similar campaigns may have influenced the willingness of control participants to quit or attempt to quit, which could attenuate the potential effects of the study intervention. The relationships of these variables in the context of the hypothesized theoretical model are shown in **Figure 1**.

Figure 1. Hypothesised conceptual framework.



Conceptual Hypothesis

H1. Group tobacco cessation behavioural interventions (combined motivational interviewing and CBT) increases quit attempts among patients with mental illness.

H2. There is an association between tobacco use changes to the changes in health-related quality of life among patients with mental illness.

H3. Patients experience different barriers in their quit attempts.

H4. Patients involved in group tobacco cessation behavioural interventions Incorporate their own facilitators during their quit attempts.

CHAPTER THREE: METHODS

Study Design

This study used a randomised clinical trial design.

Study Setting

This study was conducted at Mathari Referral and Teaching Hospital Clinic for Substance Abuse Treatment (CSAT) and outpatient follow-up clinics. Mathari Referral and Teaching Hospital is Kenya's only national referral and teaching psychiatric hospital with a capacity of 700 psychiatry beds. The staff who provide services at the hospital include 243 nurses, 11 psychiatrists (2 of whom are full-time administrators), 2 pharmacists, 5 clinical officers, 3 social workers, and support staff. Tobacco cessation therapy was provided by tobacco cessation counsellors trained by the researcher. The study was conducted at the CSAT and other outpatient clinics.

Inclusion and Exclusion Criteria

Inclusion criteria:

1. 18 years of age and above.
2. History of tobacco use for more than 6 months.
3. A Fagerstrom score of 6 and above, which is a threshold consistent with dependence.[124]
4. Currently on outpatient follow up treatment for a diagnosed mental health condition.
5. Willing to be part of the study for 6 months.

Exclusion criteria:

1. Patients on nicotine replacement therapy (NRT) or other pharmacotherapy for tobacco cessation.
2. Patients currently experiencing severe psychotic episodes judged by their treating health care provider.
3. Patients who would not be able to commit to the group sessions, defined as those who would not be able to attend group sessions for any reason, including transport-related reasons.

Sample Size Calculation

The sample size necessary for comparing proportions: proportion p_1 being the estimated proportion of study participants with improved health status after the intervention and p_2 being the estimated proportion of study participants with improved health outcomes in the control group.[125]

$$n = (\frac{r+1}{r}) \frac{(\bar{p})(1-\bar{p})(Z_{\beta} + Z_{\alpha/2})^2}{(p_1 - p_2)^2}$$

Table 3.1: Sample size calculation.

Ratio of intervention: controls (r)	1
Estimated proportion with improved outcomes in intervention group p_1	0.35
Estimated proportion with improved outcomes in control group p_2	0.15
Odds ratio	3.05
Average of proportions $(p_1 + p_2)/2$	0.25
Power (1-α/2)	0.95

Power (1-β)	0.80
Sample size per group	37
Sample size per group after adjusting for 30% attrition rate	48
Total sample size	**96**

Allocation of Participants

Table 3.1 presents the sample size, allocation of participants to the intervention and control groups, and estimated proportion with improved outcomes in intervention group and in control group, while factoring in attrition rates.

All patients who were enrolled for follow-up programs at CSAT and follow-up clinics (outpatient follow-up for the mental health condition review) were asked about their history of tobacco use by the intake/registration nurses.

All patients who walked in for follow-up after hospital discharge for a primary mental health diagnosis were screened for tobacco use using the Fagerstrom test. From March 2017 to February 2019, this screening continued until the number of participants who provided informed consent reached 100. Participants were recruited in clusters of 10 for prospective allocation into the intervention and control groups. The first 10 participants formed group 1, and the next 10 participants formed group 2. Group 1 became the first intervention group, while group 2 became the first control group. This procedure continued until all 10 groups were formed (5 intervention and 5 control groups).

Clinic patients who used tobacco were informed of the study and were invited to participate. Informed consent (Appendix 1) was obtained from individuals who had capacity to provide informed consent in the presence of the clinicians working with

the participants to ensure they understood the study requirements. Individuals who did not have capacity to provide informed consent (according to the clinician on site) were not recruited to minimize potential risks to this vulnerable population. After providing informed consent, participants were asked to complete the Fagerstrom tobacco use test (Appendix 2). Participants were asked to complete sociodemographic questionnaire (Appendix 3) and the World Health Organization (WHO) HRQoL questionnaire (Appendix 4). The questionnaires were researcher administered to participants who had low literacy. Participants continued with their regular clinic follow-up for ongoing mental health care on their regular clinic days.

Study Intervention

Prior to recruitment, the researcher trained 2 counsellors who assisted with recruitment, screening, intake, and registration. Two addiction therapists who did not work at the hospital were trained by the researcher to lead tobacco cessation groups tailored to psychiatric patients.

5As-based brief advice was offered to the intervention group participants by the study team who were trained by the researcher (Appendix 5). This brief advice consisted of an individual session lasting approximately 5 minutes for each participant immediately after their consent had been obtained. The focus of the 5As was to enable the therapist to understand the immediate concerns of each participant and to enable adequate support when the particular issues were raised during the group intervention sessions. The behavioural group tobacco cessation intervention (Appendix 6) consisted of 6 sessions over 12 weeks and were led by 2 trained facilitators, followed by monthly group meetings from weeks 14 to 26. This program was adapted from the Royal Australian College of General Practitioners'

Supporting Smoking Cessation Guide for Health Professionals and the World Health Organization's *Strengthening Health Systems for Treating Tobacco Dependence in Primary Care* training package.[126, 127]

The session topics as covered during the bi-weekly meetings are shown in **Table 3.2**.

Table 3.2: Study intervention timeline and content.

Time Frame	Group sessions
After signed consent	5 As (Ask, Advice, Assess, Assist, Arrange)
Session 1 (Week 1)	1. Introduction to the program and reasons to quit
Session 2 (Week 3)	2. Benefits of quitting and understanding why we smoke and ways of quitting setting quit date
Session 3 (Week 5)	3. Withdrawal symptoms and social support
Session 4 (Week 7)	4. Dealing with stress and anxiety and coping with depression
Session 5 (Week 9)	5. Assertiveness training and anger management
Session 6 (Week 11)	6. Tobacco-free lifestyle and dealing with high risk situations
Follow up sessions (Weeks 14-26)	7. Round of discussion on participants' feelings, cessation attempts, barriers experienced, and how they coped 8. Documentation of self-reported quit attempts 9. Support offered as per participants experiences/challenges

Group Session 1 (Week 1)

On the first session, participants were introduced to the study program and specific components of the group behavioural intervention. Participants shared their

expectations and experiences in their goal of tobacco cessation. The estimated time for group session 1 was 30 to 45 minutes. All sessions were in English, Kiswahili or Sheng' (local dialect) as directed by the participants.

Group Sessions 2-6 (Weeks 2-11)

Participants set their anticipated quit date on the 2nd week, which was their second session. During weeks 2 through 11, before the start of the session, the previous week's self-reported tobacco consumption or cessation attempt was recorded. The topic of each week was explored first by lecture to explain the topic, and then group members took turns sharing their experiences on the topic.

Group Sessions 7-9 (Weeks 14-26)

Participants continued attending the CSAT outpatient and ward follow-up programs during this period. Behavioural group sessions 7-9 (weeks 14-26) were conducted once a month by the facilitators whereby each session was begun with a round of discussion on how participants were feeling about their cessation attempts, including any barriers they had experienced. The self-reported amount of tobacco used and quit attempts were documented. The study team also documented the barriers raised and tried to offer practical and supportive therapy for the barriers.

The activities undertaken during the different follow-ups periods and how they were documented are presented in **Table 3.3**.

Table 3.3: Baseline and follow-up assessments.

Follow-up time	Activity	Documentation
Week 0 (Baseline)	• Socio-demographic questionnaire • Fagerstrom test for nicotine dependence • WHOQOL-BREF instrument	• Age of first use, duration of use, amount used, mental illness managed, other substances used • Fagerstrom test score • WHOQOL-BREF score
Week 4	• Explored progress made and documented quit attempts (focused group discussion) • Focused on barriers experienced and how they were managed (focused group discussion) • Documented number of sticks currently smoked • Those reporting complete cessation and who gave consent for saliva testing, were then screened using cotinine test	• Quit attempts made • Amount currently being smoked • Salivary cotinine test • Note taking
Week 12	• Explored progress made and documented quit attempts (focused group discussion) • Focused on barriers experienced and how they were managed (focused group discussion) • Documented number of sticks currently smoked	• Quit attempts made • Amount currently being smoked • Salivary cotinine test • Note taking

	• Those reporting complete cessation and who gave consent, were screened using cotinine test	
Week 26 (Final follow-up)	• Explored progress made and documented quit attempts (focused group discussion) • Focused on barriers experienced and how they were managed • Documented number of sticks currently smoked • Those reporting complete cessation, gave consent, then were screened using cotinine test • Administered WHOQOL-BREF instrument	• Recorded quit attempts made • Amount currently being smoked • Salivary cotinine test • WHOQOL-BREF score

Based on previous tobacco cessation intervention trials, it was assumed that those who did not report abstinence had positive cotinine results.[128]

Control Group Procedures

The control group was provided questionnaires to fill at the end of weeks 4, 12, and 26. During the rest of the study, they continued receiving usual care, including clinical care at CSAT. After the conclusion of the study, the control group was offered the group sessions that the intervention group received.

Outcome Measures

At the group assessments (weeks 4, 12, and 24), participants who reported total tobacco use abstinence and consented to a saliva test were tested using a nicotine cotinine strip (Devon Medical, Pennsylvania, USA: Nicotine/tobacco test kit). Saliva tests were evaluated by the nurses working at the hospital who were blinded to treatment allocation and were not otherwise part of the study.

The primary outcome was self-reported tobacco use abstinence at week 24, which was biochemically verified. Secondary outcomes assessed included: cessation at week 4 and week 12, number of quit attempts, reduction in number of cigarettes used per day, and HRQoL measured at week 26.

Research Instruments

5As: Stages in the process of smoking cessation

The tobacco cessation research literature strongly supports the use of a comprehensive, clinic-based approach to tobacco cessation, known as the 5A's—Ask, Advise, Assess, Assist, and Arrange follow-up. Most clinicians have found the first 3 As (Ask, Advice, Assess) to be easy to use and highly effective, while the last 2 As (Assist and Arrange) are less commonly used.[129]

Fagerstrom test

The Fagerstrom Test for Nicotine Dependence (FTND) is a widely used and researched short questionnaire.[124] The FTND has been found to have good test-retest reliability, convergent validity, and discriminant validity and performs well from a psychometric perspective with smokers with mental illness as it does with smokers without mental illness.[130] Several studies analysis on the reliability index for the

overall score on the FTND indicated that it was excellent (0.87). In 14 studies that evaluated the internal consistency of the FTND, the Cronbach's alpha coefficient ranged from 0.55 to 0.74, indicating that the FTND has moderate internal consistency.[131] The FTND can be administered in an interview or tobacco users can self-administer the questionnaire. The score ranges from 0–10 points, and the mean score of representative samples of smokers is usually in the range of 3–4 points.

World Health Organization Quality of Life-100

The World Health Organization developed the World Health Organization Quality of Life-100 (WHOQOL-100) as a cross-cultural method of assessing QOL separate from a specific disease. Defining quality of life as an "individual's perceptions of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards, and concerns".[132] The WHOQOL-BREF is a shorter version of the WHOQOL-100. It allows the respondent to determine his or her satisfaction while limiting constraints from cultural expectations or developer biases. It has been translated into 19 languages.

The WHOQOL-BREF has been validated for use in mental health populations.[133] The short/brief version (WHOQOL-BREF) was used in this study to assess quality of life. It has 26 questions, 24 of which are grouped into 4 domains (i.e. physical health, psychological, social relationships, and environmental). The total scores from each domain are arrived at through adding the values of each response; the WHOQOL BREF instrument uses a Likert scale ranging from 1 to 5.

Raw domain scores were transformed to a 4-20 score according to the WHOQOL-BREF guidelines. Domain scores were scaled in a positive direction

(higher scores denote higher HRQoL). Mean scores within each domain were used to calculate the domain scores.

Project Team

- The researcher trained 1 research assistant, 2 nurses, and 2 counselors who were part of the study.
- 2 nurses who were part of the hospital staff, who were working at the outpatient registry were recruited to assist in identification of all patients who use tobacco and screened them for eligibility for the study.
- 2 counselors who were not part of the hospital team were trained by YO in tobacco cessation group therapy to lead in facilitation of the group sessions.

Ethical Considerations

The research proposal was presented to the department of Psychiatry University of Nairobi (UoN) for study clearance approval. The study and associated protocol were approved by the ethical committee of Kenyatta National Hospital in February 2017. The trial and its protocol were registered in May 2018 by the National Commission for Science, Technology and Innovation (NACOSTI); Permit No: NACOSTI/P/18/37962/21104 and ClinicalTrials.gov in July 2019. Identifier no: NCT04013724.

Eligible participants for this study were those who were mentally stable and were in a position to provide informed consent. For those eligible participants who did not understand English nor Kiswahili, a translator was availed for them from a member of the research team trained in responsible conduct of research. If a translator was not readily available, then the participant was given another date to come back when a translator would be available. All participants were briefed on the

purpose of the study. The study did not anticipate any more than minimal risk to the participants through their participation because those who had serious withdrawals, as described by the participants, would not be included and would be referred for appropriate interventions. YO is a trained mental health specialist, has been trained in research among vulnerable populations, oversaw the study interventions on site, and participated in facilitating the interventions.

Each screened individual was assured of confidentiality and allowed to ask questions or clarifications prior to participating in the study. Also, participants were enrolled using their client codes to protect their identities, and any identifying information was stored in a password-protected, securely stored file by YO. Considering that the study asked questions that might have made the respondents uncomfortable, those who chose to participate were informed of these risks during the informed consent process for the study, and they were also informed that they had the right to withdraw at any time without any repercussions. In case a client withdrew from the study, they were assured that they would continue benefiting from all the hospital services as other patients, ensuring the principle of justice was upheld. The study had safety precautions for participants such that any participant who was found to need further psychological services (e.g. severe withdrawal, confusion, or some form of psychosis) would be referred to the appropriate clinical program or facilities where necessary or advised to seek further management. No such measures were needed.

Dissemination of results is planned through publications in peer-reviewed journals and presentations in scientific conferences. Results will also be disseminated through presentations in local mental health meetings and within the study site.

Participants' Incentives

Participants were reimbursed Kshs. 200 (approximately USD $2) for transport and time spent at the hospital because of the study.

Data Collection and Management

Data was collected using structured questionnaires, recordings and transcriptions of focused group discussions and entered into a secure, password-protected database. The hard copy data forms were stored in a lockable cabinet in lockable office after collection, data entry, analysis, and after study completion. Upon completion of data entry, 20% of hard copy forms were compared with the entered data to identify systematic or random errors and corrections and repeated data entry were made appropriately.

Sociodemographic characteristics of the study participants, such as age, sex, residence, education level, occupation and perceived health status, were reported. Participants' health-related quality of life at baseline was assessed using the WHOQOL-BREF. The type of tobacco product under use, daily amount of tobacco consumption, duration of use, and age of initiation to tobacco was also described. Using the Fagerstrom test, nicotine dependency was determined and intent to quit use of tobacco products was described. Data on any other substance use such as alcohol, bhang and khat, including duration of use, was also reported.

Qualitative data were captured using focused group discussions (Appendix 7) during the tobacco group behavioural intervention sessions. The discussions captured participants' experiences with nicotine withdrawals and other barriers and the facilitators they found to be effective, particularly those strategies they

incorporated that were not part of the study's intervention program. Qualitative data was recorded through notetaking by YO and a research assistant during the group intervention sessions.

Data Analysis

For quantitative data analysis, discrete variables were summarized using frequencies and percentages, while continuous variables were summarized using measures of central tendency and dispersion such as means with standard deviations and median with inter-quartile ranges, where appropriate. Bivariate analyses were carried out to compare the intervention groups with the control groups with respect to socio-demographic characteristics, history of tobacco and substance abuse, type(s) of mental illness, and WHOQOL-BREF scores at baseline. Mann-Whitney tests were used to compare the intervention and control groups for continuous variables, and Chi-square tests were used for categorical variables. Unadjusted and adjusted cessation rates at 6 months were compared between groups using a complete case study analysis, recognizing the limitations of the study design at eliminating potential confounders between groups given the non-randomized nature of group allocation. Potential moderators included age, sex, baseline tobacco use (number per day), and baseline type of mental illness, as these are mostly the underlying factors as well as perpetuating factors to tobacco use.

Rates of tobacco cessation and reduction of tobacco use were compared between groups by Cox proportional hazard models to determine the effect of the intervention on study outcomes at 24 weeks. Logistic regression models were created to compare odds of any improvement in health-related quality of life from baseline to 24-week follow-up. Unadjusted and adjusted models were reported, the

latter which aimed to control for independent factors associated with relapse, including age, sex, baseline tobacco use (number per day), and baseline type of mental illness. Paired t-test analyses for secondary outcomes were also performed. Imputation was not used to account for missing data, and a complete case analysis was performed. A two-sided $p<0.05$ was used to determine statistical significance without adjustments to account for multiple testing. All analyses were carried out using IBM SPSS Statistics Software, Version 24.

Qualitative data were analysed using an inductive approach, allowing identification of emerging themes from the data. The research team focused firstly on individual group notes before seeking common themes across all the groups' data. Handwritten notes were transcribed in to electronic format (Microsoft Word initially and subsequently transferred to Microsoft Excel; one comment per excel cell) by the researcher and checked by another member of the study team.

Comments from each group were cross-referenced and compared ensuring all comments were recorded accurately while duplicate entries were removed. Final list of focus comments was compiled for coding. Themes were identified by applying colour codes to cells. Microsoft Excel's filter was applied to the data to sort by cell colour and thus thematic area. A second pass over the data identified overlapping comments and comments and themes were consolidated. Codes applied were keywords to categorize or organize text into themes by the PI, and data were analysed in accordance with the process described by Braun and Clarke.[134] The next stage involved interpreting the data by identifying any recurring themes throughout and highlighting similarities and differences in the content across groups. The final stage involved content verification that involved rechecking the progress notes and codes again.

The summary of the analysis plan is shown in **Table 3.4**.

Table 3.4. Summary of objectives, hypotheses, statistical tests, and models.

Objectives	Hypotheses	Statistical Tests	Models
1. To evaluate the effect of group tobacco cessation behavioural interventions among patients with MI	H1. Group tobacco cessation behavioural interventions increases quit attempts among patients with mental illness.	Cox proportional hazards regression models	Outcome (y)=tobacco cessation Predictors (hazard function), (x_i)=intervention, time-dependent covariates *Model:* $y = \beta_1 x_1 + \beta_2 x_2 + \ldots + \varepsilon$ Where β is the coefficient and ε is a constant
2. To analyze the association between tobacco use changes to the changes in quality of life among the patients	H2. There is an association between tobacco use changes to the changes in quality of life among patients with mental illness	Pearson's correlation coefficient	Outcome (y) = tobacco use changes Correlate (x) = quality of life
3. To identify barriers patients experience in their quit attempts	H3. Patients experience different barriers in their quit attempts	Qualitative tests	Results analyzed by themes

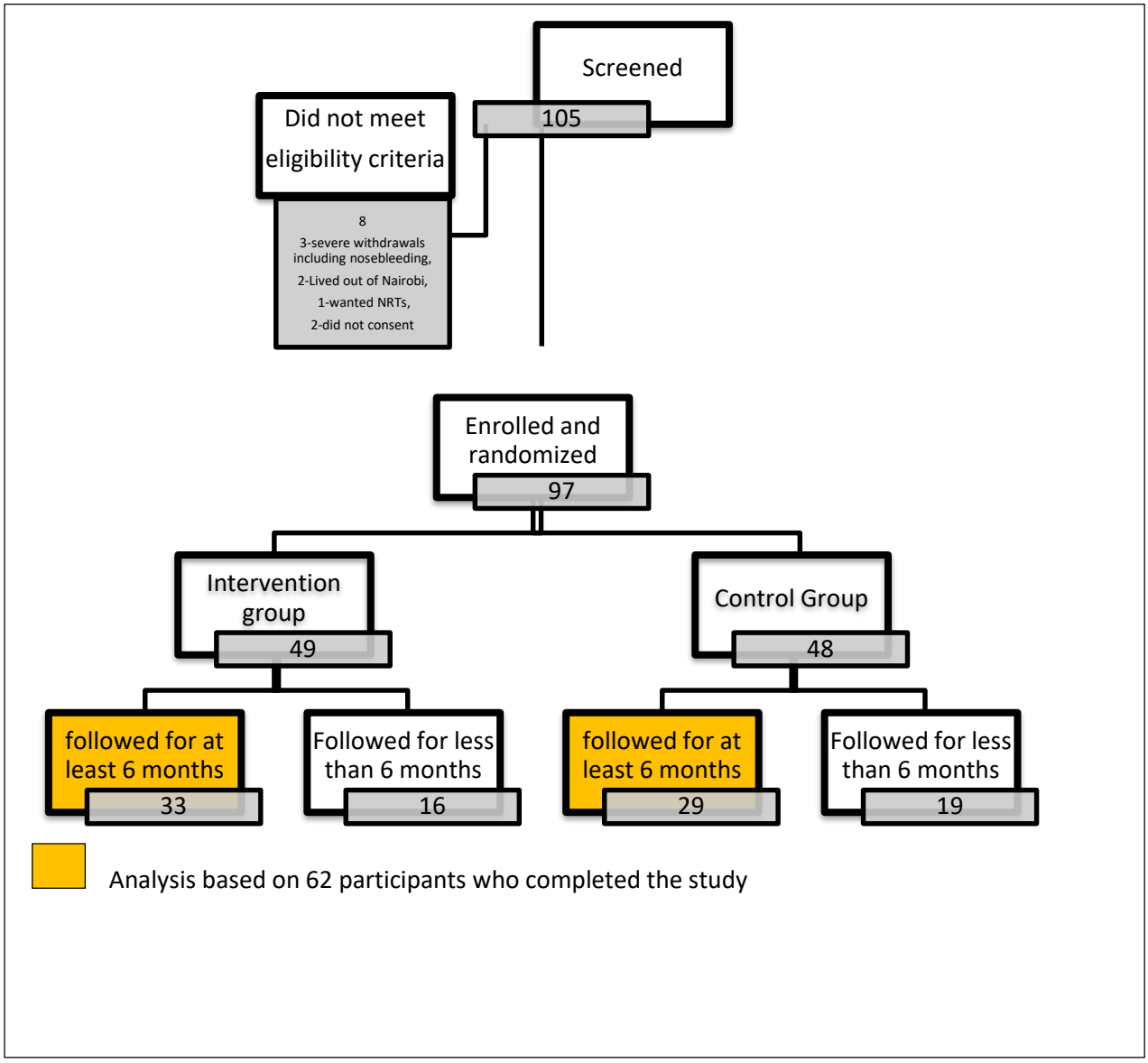
4. To find out interventions used by patients in their quit attempts	H4. Patients involved in group tobacco cessation behavioural interventions incorporate their own strategies during their quit attempts	Qualitative tests	Results analyzed by themes

CHAPTER FOUR: RESULTS

Trial Participant Flow

Among 105 participants screened, 97 participants were recruited, and 16 (32.7%) in intervention group and 19 (39.6%) in the control group were lost to follow-up over the 24-week study period (**Figure 2**).

Figure 2: Randomised clinical trial flow chart for the group behavioural tobacco cessation intervention.



Socio-demographic characteristics

Table 4.1 outlines the baseline characteristics of the participants. Mean (SD) age of participants was 35 (9) years, and most (87%) were male. Less than half (40%) were unemployed with a similar number (35%) being self-employed. Most participants (65%) had a history of substance use disorder, while almost three-quarters (74%) reported using other drugs. From the participants' medical records, 15 % had major depression, 7% schizophrenia, and 9% bipolar disorder. Almost all participants (94%) reported using cigarettes, with only 4% using kuber. There were more men allocated to the intervention group (94%) compared with the control group (78%, p=0.02), but the group characteristics were otherwise similar.

Table 4.1: Baseline socio-demographic characteristics.

		Intervention N=49	**Control N=48**	**OR [95% OR]**	**P value**
Age, years, mean (SD)		33.4 (6.0)	36.1 (11.4)	1.03 [0.99-1.08]	0.15
Male sex, n (%)		38 (78)	45 (94)	4.34 [1.13-16.71]	0.02
Number smoked/chewed per day, mean (SD)		12.9 (7.0)	13.9 (6.5)	1.03 [0.97-1.09]	0.43
Years using tobacco, mean (SD)		11.6 (6.4)	12.7 (10.8)	1.01 [0.97-1.06]	0.57
Age of first tobacco use, mean (SD)		19.5 (5.3)	22.1 (8.8)	1.06 [0.99-1.12]	0.08
Fagerstrom score		5.9 (1.5)	5.7 (1.7)	0.92 [0.72-1.18]	0.52
Primary tobacco product				0.31 [0.03-3.11]	
Cigarette		48 (98)	45 (94)		0.30
Kuber		1 (2)	3 (6)		
Primary mental health disorder	Substance use disorder	39 (79.6)	26 (54.2)	-	0.06

	Major depression	4 (8.2)	11 (22.9)	-	
	Schizophrenia	2 (4.1)	5 (10.4)	-	
	Bipolar	3 (6.1)	6 (12.5)	-	
	Depression	1 (2.0)	0 (0)	-	
	None	1 (2.0)	0 (0)	Ref	
	Primary	15 (30.6)	14 (29.2)	0	
	Secondary	22 (44.9)	19 (39.6)	0.19 [0.02-1.80]	
Education level completed	College (1-2 years post high-school)	10 (20.4)	10 (20.8)	0.17 [0.02-1.61]	0.42
	University (>4 years post high-school)	1 (2.0)	5 (10.4)	0.20 [0.02-2.03]	
	Unemployed	22 (44.9)	15 (31.3)	Ref	
	Student	3 (6.1)	0 (0)	0	
Occupation	Self employed	12 (24.5)	21 (43.8)	2.57 [0.98-6.75]	0.10
	Employed	12 (24.5)	11 (22.9)	1.34 [0.47-3.84]	
	Retired	0 (0)	1 (2.1)	>1000	
	Poor	7 (14.3)	9 (18.8)	Ref	
Self-assessed general health	Fair	20 (40.8)	17 (35.4)	0.67 [0.20-2.15]	0.79
	Good	22 (44.9)	22 (45.8)	0.78 [0.25-2.46]	
Use of alcohol and other drugs	Yes	33 (70.2)	37 (77.1)	ref	0.45
	No	14 (29.8)	11 (22.9)	0.70 [0.28-1.76]	

Completers versus non-completers

Characteristics comparing study completers versus non-completers are reported in **Table 4.2,** which demonstrates the similarities between the two groups.

Table 2: Characteristics of participants who completed study versus those who did not.

		Participants characteristics					
		Did not complete study		Completed study			
		N=35	**%**	**N=62**	**%**	**OR [95% CI]**	**p-value**
gender	Male	31	37.3%	52	62.7%	ref	0.53
	Female	4	28.6%	10	71.4%	1.49 [0.43-5.16]	
Education level	None	0	0.0%	1	100.0%	Ref	0.09
	Primary	6	20.7%	23	79.3%	0	
	Secondary	17	41.5%	24	58.5%	0	
	College	11	55.0%	9	45.0%	0	
	University	1	16.7%	5	83.3%	0	
Occupation	Unemployed	12	32.4%	25	67.6%	Ref	0.54
	Student	0	0.0%	3	100.0%	>1000	
	Self employed	14	42.4%	19	57.6%	0.65 [0.25-1.73]	
	Employed	9	39.1%	14	60.9%	0.75 [0.25-2.21]	
	Retired	0	0.0%	1	100.0%	0	
General health	Poor	6	37.5%	10	62.5%	0	0.84
	Fair	12	32.4%	25	67.6%	1.25 [0.37-4.25]	
	Good	17	38.6%	27	61.4%	0.96 [0.29-3.10]	
Mental health disorder	Substance dependence	24	36.9%	41	63.1%	Ref	0.59
	Major depression	6	40.0%	9	60.0%	0.89 [0.29-0.28]	
	Schizophrenia	2	28.6%	5	71.4%	1.46 [0.26-8.14]	
	Bipolar	2	22.2%	7	77.8%	2.05 [0.39-10.67]	
	Depression	1	100.0%	0	0.0%	0	
	Anxiety	0	0.0%	0	0.0%	0	
Tobacco product	Cigarettes	34	36.6%	59	63.4%	Ref	0.64
	Kuber	1	25.0%	3	75.0%	1.73 [0.17-17.28]	
	Shisha	0	0.0%	0	0.0%	-	

Smokeless tobacco	0	0.0%	0	0.0%	-

Tests of the hypotheses

Discrete variables were summarized using frequencies and percentages, while continuous variables were summarized using measures of central tendency and dispersion such as means with standard deviations and median with inter-quartile ranges, where appropriate.

Between group events rates of tobacco use were compared between groups by Cox proportional hazard models to determine the effect of the intervention on the primary study outcome. Unadjusted and adjusted models were reported, the latter which aimed to control for independent factors associated with relapse.

The two-sided $p<0.05$ was used to determine statistical significance without adjustments to account for multiple testing. All outcomes that were found to be significant rejected the null hypothesis.

H1. Group tobacco cessation behavioural intervention increases quit attempts among patients with mental illness.

The first objective was to evaluate the effect of group tobacco cessation behavioural interventions among patients with mental illness. This objective informed Hypothesis 1: Group tobacco cessation behavioural intervention increases quit attempts among patients with mental illness.

This hypothesis sought to establish the influence of group tobacco cessation behavioural intervention on reduction in amount of tobacco used as well as successful quit attempts.

Primary Outcome: Tobacco Cessation Rate biochemically verified

For the primary study outcome, the rate of biochemically-verified tobacco cessation in the intervention group was 15.2% (5/33) versus 0% (0/34) at week 12 (P= 0.02) and 9.1% (3/30) versus 0% (0/29) at 24 weeks (P=0.10). No participant in the control group successfully quit (**Table 4.3**).

Table 4.3: Successful cessation biochemically verified at 12-week and 24-week follow-up.

		Intervention		Control		
		N=33	**%**	**N=29**	**%**	**p-value**
Cessation at 12-week follow-up	No	28	84.8	34	100.0	0.02
	Yes	5	15.2	0	0.0	
Cessation at 24-week follow-up	No	30	90.9	29	100.0	0.10
	Yes	3	9.1	0	0.0	

Comparison between intervention and control groups- Reduction in amount smoked

When comparing the reduction in amount smoked at baseline to 12-week and 24-week follow-up, the intervention group reduced the number of cigarettes or kuber smoked more than the control group at week 12 (mean (SD) 3.42 (3.52) sticks in the intervention group versus 11.65 (5.77) sticks in the control group, P<0.001) and week 24 (mean (SD) 5.78 (6.37) sticks in the intervention group versus 12.17 (6.89) sticks in the control group, P<0.0001, **Table 4.4**).

Table 4.4: Amount smoked at baseline, 12-week follow-up, and 24-week follow-up among trial participants.

	Group		
	Intervention	**Control**	**p=value**
	n=49	**n=48**	

Number of sticks at baseline	Mean (SD)	12.88 (7.03)	13.96 (6.45)	0.43
	Median (IQR)	9 (8,16)	14 (9,16)	
		n=33	**n=34**	**p=value**
Number of sticks at Week 12	Mean (SD)	3.42 (3.52)	11.65 (5.77)	<0.0001
	Median(IQR)	2 (1,5)	11(7,15)	
		n=33	**n=29**	**p=value**
Number of sticks at Week 24	Mean (SD)	5.78 (6.37)	12.17 (6.89)	<0.0001
	Median (IQR)	2 (1,10)	10 (7,16)	

Reduction in the number of cigarettes smoked or kuber chewed over study period

When comparing changes in the amount smoked at the end of the 24-week study period among individuals who completed the study, intervention group participants reduced the number of cigarettes or kuber smoked more than the control group participants (intervention group median [IQR] reduction: 8 [6, 13] cigarettes or kuber vs control group median [IQR] reduction: 2 [-2, 6] cigarettes or kuber, P<0.0001, **Table 4.5**).

Table 4.5: Reduction in the number of cigarettes or kuber smoked over the study period, by intervention and control group.

	Intervention (N=33)	**Control (N=29)**	**p-value**
Number smoked at start, median (IQR)	9 (8, 16)	14 (9, 16)	0.68
Number smoked at study end, median (IQR)	2 (1, 3)	10 (7, 16)	<0.01

Reduction in number smoked, median (IQR)	8 (6, 13)	2 (-2, 6)	<0.01
Proportion of reduction (95% CI)	97.0% (90.8%, 100%)	58.6% (39.6%, 77.7%)	<0.0001

These details are presented in **Figure 3**.

Figure 3: Box plot showing number of reductions in the number of cigarettes or kuber smoked over the study period, by intervention and control group.

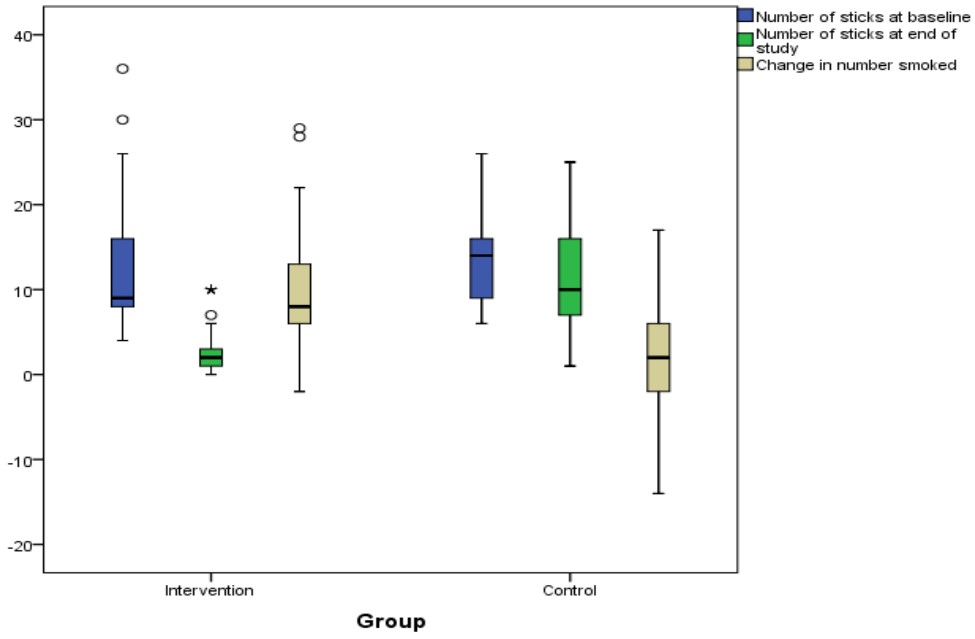
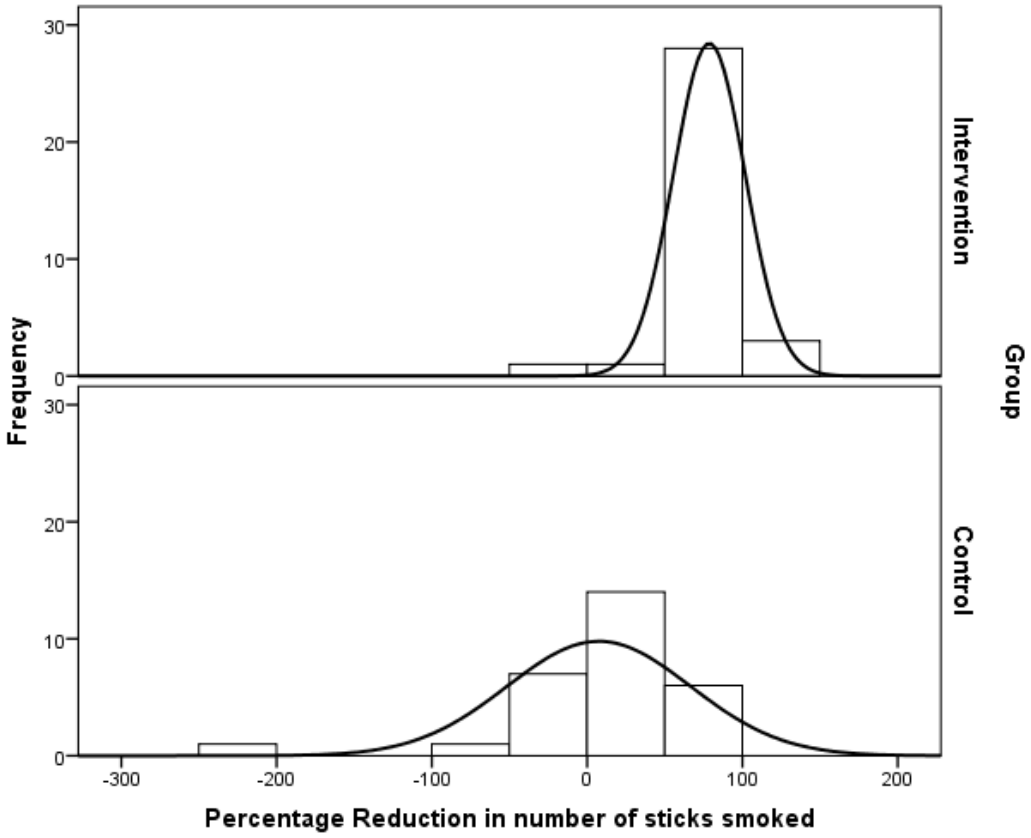


Figure 4 depicts a visual representation of reduction percentage of cigarettes smoked. **Figure 4. Histograms of reduction in number of cigarettes smoked in**

intervention and control groups.



Successful Quits with Alternative Definition

When defining successful quits as a reduction to smoking less than 2 cigarettes or kuber per day, then the rate in the intervention group was 46% compared to 3% in the control group (P=<0.0001, **Table 4.6**), which was statistically and clinically significant.

Table 4.6: Tobacco use reduction to less than 2 cigarettes or kuber per day among study participants at study end.

	Intervention	Control	
	N (33)	N (29)	p-value

Cigarettes or kuber remaining	Less than 2 cigarettes or kuber per day	15 (45.5%)	1 (3.4%)	<0.0001
	2 or more cigarettes or kuber per day	18 (54.5%)	28 (96.6%)	

Cox Proportional Hazards Regression Models for Reducing Smoking

The unadjusted results showed that participants in the intervention group were almost 14 times more likely to reduce smoking than participants in the control group (97.0% vs 58.6%, HR 13.85 [95% CI, 3.95-48.59]). After adjusting for covariates that potentially confound the relationship between mental illness and cigarette smoking and that have documented association with smoking,[135] the direction and magnitude of effect were similar (HR 14.92 [95% CI, 4.06-54.86]).

Table 4.7: Cox proportional hazards regression models for the outcome of any reduction in smoking.

Covariates	**Unadjusted**	**95% CI**		**Adjusted**	**95% CI**	
	HR	**Lower**	**Upper**	**HR***	**Lower**	**Upper**
Group (Intervention)	13.85	3.95	48.59	14.92	4.06	54.86
Age	0.99	0.95	1.03	0.97	0.93	1.00
Sex (Males)	1.99	0.92	4.34	3.03	1.16	7.92
Fagerstrom	1.01	0.85	1.19	1.25	1.02	1.52
Use of AOD	1.05	0.54	2.03	0.79	0.40	1.59

*Adjusted for age, sex, baseline tobacco use, and baseline type of mental illness.

AOD -Alcohol and other drug use, but not diagnosed as a substance use disorder

H2. There is an association between tobacco use changes to the changes in quality of life among patients with mental illness

The second objective was to analyse the association between tobacco use changes to the changes in quality of life among the patients. This objective informed Hypothesis 2: There is an association between tobacco use changes to the changes in quality of life among patients with mental illness.

This hypothesis sought to analyse the impact of tobacco cessation or reduction on the quality of life of the participants.

Health-Related Quality of Life Scores and Intervention Outcome

Mean health-related quality of life scores at baseline and 24-week follow-up in the intervention and control groups are reported in **Table 4.8**. When comparing the four domains in the instrument (i.e. physical, psychological, social relationships, and environment) at baseline and 24-week follow-up, they were numerically higher in the intervention group compared to the control group, but these differences were not statistically significant.

Table 4.8: Mean changes in health-related quality of life among the different domains at baseline and end of 24-week study period.

Domains	Duration Period	Intervention		Control		Intervention vs Control
		Mean (SD)	p-value	Mean(SD)	p-value	p-value
Physical	Baseline	12.99(3.19)		14.51(1.89)		0.004
	24-week follow-up	13.90(2.71)	0.12	12.78(2.61)	0.47	0.48
Psychological	Baseline	13.27(2.83)		13.88(2.39)		0.20
	24-week follow-up	13.62(2.26)	0.88	12.56(2.00)	0.29	0.24

Social relationships	Baseline	12.65(3.51)		13.22(2.98)		0.59
	24-week follow-up	12.81(3.54)	0.08	11.51(2.60)	0.51	0.15
Environment	Baseline	12.57(3.18)		14.56(3.46)		0.01
	24-week follow-up	13.24(2.84)	0.44	11.94(1.42)	0.50	0.20

Health-Related Quality of Life Outcomes after Intervention

Changes in health-related quality of life in the intervention and control groups among individuals who completed the 24-week follow-up period are reported in **Table 4.9**. Participants in the intervention group were more likely to experience greater improvement in physical (30.6% vs 10.4% OR=3.79 [95% CI, 1.25-11.48]) and environmental health (34.7% vs 8.3%, OR=5.84 [95%, 1.79-19.03]) domains (P<0.01 for both), but changes in other domains were similar between groups.

Table 4.9: Any improvement in health-related quality of life score between intervention and control groups measured by WHOQoL with corresponding odds ratio for any improvement.

Domains		Intervention	Control		
		N=33	N=29	OR (95% CI)	p-value
Physical health	Yes	15 (30.6%)	5 (10.4%)	3.79 (1.25, 11.48)	0.01
	No	34 (69.4%)	43 (89.6%)		
Psychological	Yes	14 (28.6%)	8 (16.7%)	2.00 (0.75, 5.33)	0.16
	No	35 (71.4%)	40 (83.3%)		
Social relationships	Yes	15 (30.6%)	8 (16.7%)	2.21 (0.83, 5.83)	0.11
	No	34 (69.4%)	40 (83.3%)		
Environment	Yes	17 (34.7%)	4 (8.3%)	5.84 (1.79, 19.03)	<0.01
	No	32 (65.3%)	44 (91.7%)		

Yes: Increased score; No: No improvement

Domain-Specific adjusted HRQOL scores

Domain-specific, adjusted results are reported in **Table 4.10**, which showed a similar direction to the overall results with better quality of life in the environment domain among individuals randomized to the study intervention group (adjusted OR 6.46 [95% CI 1.79-23.34]).

Table 4.10: Adjusted outcomes for health-related quality of life.

Physical domain						
	Coefficient	**S.E. of coefficient**	**p-value**	**OR**	**95% C.I. for OR**	
					Lower	**Upper**
Group	1.12	0.61	0.07	3.06	0.93	10.13
Age	0.01	0.03	0.78	1.01	0.94	1.08
Gender	0.93	0.72	0.20	2.53	0.61	10.43
Use of AOD	1.35	0.60	0.03	3.85	1.19	12.51
Mental health disorder	-.39	0.35	0.28	0.68	0.34	1.36
Psychological domain						
	Coefficient	**S.E. of coefficient**	**p-value**	**OR**	**95% C.I. for OR**	
					Lower	**Upper**
Group	0.43	0.55	0.44	1.54	0.52	4.53
Age	0.04	0.04	0.30	1.04	1.00	1.11
Gender	-.353	0.75	0.64	0.70	0.16	3.06
Use of AOD	0.53	0.63	0.41	1.70	0.49	5.87
Mental health disorder	-1.62	0.73	0.03	0.20	0.05	0.83
Social domain						
	Coefficient	**S.E. of coefficient**	**p-value**	**OR**	**95% C.I. for OR**	
					Lower	**Upper**
Group	0.83	0.54	0.12	2.30	0.80	6.66
Age	0.04	0.03	0.14	1.04	0.99	1.11
Gender	0.77	0.67	0.25	2.16	0.58	8.08
Use of AOD	0.26	0.57	0.65	1.29	0.43	3.92
Mental health disorder	-.18	0.28	0.52	0.84	0.49	1.44
Environment domain						
	Coefficient	**S.E. of coefficient**	**p-value**	**OR**	**95% C.I. for OR**	
					Lower	**Upper**
Group	1.87	0.66	0.004	6.46	1.79	23.34
Age	0.05	0.04	0.19	1.05	0.98	1.12
Gender	-.35	0.77	0.65	0.71	0.16	3.21
Use of AOD	0.16	0.62	0.80	1.17	0.35	3.94
Mental health disorder	-.59	0.39	0.14	0.56	0.26	1.20

*Adjusted for age, gender, baseline AOD, and baseline type of mental illness.

AOD: Alcohol and other drug use, but not diagnosed as a substance use disorder

Qualitative Findings

In this section, the first part will focus on the barriers of quitting cigarettes smoking, and the second part will focus on the facilitators that participants added to the study intervention.

H3. Patients experience different barriers in their quit attempts

The third objective was to identify barriers patients experience in their quit attempts. This objective informed Hypothesis 3: Patients experience different barriers in their quit attempts.

This hypothesis sought to understand some of the barriers that patients experience while attempting to quit tobacco use; particularly while receiving the group tobacco cessation behavioural intervention.

This hypothesis was tested by thematic analysis.

Barriers were identified that delayed or prevented patients from successfully attaining their quit attempts. Participants reported barriers experienced during their quit attempts, as well as the additional facilitators they used to boost their quit attempts. Barriers highlighted during group therapy intervention studies included:

Barriers for quitting tobacco use

1. Peer influence and support

Most participants were smoking in groups, including after the group sessions or while they were working together, or “hustling” together.

"*Me, I would like to quit but after the session, when walking to the bus stop, we walk as a group and when others are smoking, I just have to. The smell of the cigarette is in your face, you just have to." (34-year-old, female)*

"When with others you don't have to worry about smoking, it is free, everyone just gives you a puff." (35-year-old, male)

"I just have to smoke when with my friends, they are the ones who support me when am stuck. If I avoid them because I have stopped smoking, what will I do when I get stuck and I don't have other friends? They might also think am the one reporting what we do. Maybe later, not now." (29-year-old, male)

2. Withdrawal symptoms

Most participants reported feeling nausea, dizziness, headaches, depressed, cravings, insomnia, coughing, moodiness and numbness associated with withdrawal, which made quitting challenging.

"In the morning, I have a serious headache that I cannot even walk. Then I feel like fainting…at such a time I have to smoke so that I feel normal. Otherwise I cannot do anything." (45-year-old, male)

3. Fear of complete cessation

Most participants had problems with quitting completely, and faced strongest urges associated with the first morning and last evening cigarettes. Others did not

want to be completely drug free, so they continued to smoke because it carried relatively lower risks compared with other drugs in terms of their daily functioning.

"Madam, I have worked on reducing smoking. I have given up alcohol and heroin. At least I need something small to keep me high." (23-year-old, male)

4. Other substance use

Most participants reported using other substances that increased their cravings. This included alcohol, methadone, bhang, and khat. Those who were using methadone reported intense cravings, especially after their daily dose of methadone. Others reported having started smoking cigarettes after initiation to the methadone program. They also had a "base" where they used to meet within the hospital just after their methadone doses and would share their cigarettes.

"*Madam, the taste of methadone is very bitter, only the taste of cigarettes takes it away. During the day (I) am able to stay without smoking, but after taking methadone, I have to take a smoke to clear the bad taste". (20-year-old, female)*

"Because I remember the effects of cigarettes smoking that you mentioned, it is better to smoke bhang…as I have to smoke something. It calms me down." (35-year-old, male)

5. End-of-month disputes

Most participants reported experiencing family disputes, housing problems, or problems with landlords that were exacerbated at the end of each month. During the

sessions, it was noted that most participants increased the number of cigarettes smoked at the end of the month. This theme was explored, and most participants reported fears of not affording their house rents and delayed payments as a serious trigger.

"It is easier to worry when you are puffing at something." (32-year-old, female)

6. Boredom

Some participants reported that they smoke more when they were idle or felt bored. But when participants were busy, they were occupied and had no time to smoke.

"When I have no work and am just relaxing, or bored, smoking keeps me busy." (31-year-old, male)

H4: Patients involved in group tobacco cessation behavioural interventions incorporate their own strategies during their quit attempts

The fourth objective was to find out interventions used by patients in their quit attempts. This objective informed Hypothesis 4: Patients involved in group tobacco cessation behavioural interventions incorporate their own strategies during their quit attempts

This hypothesis sought to understand some of the alternative facilitators patients incorporate while participating in the group tobacco cessation behavioural intervention.

This hypothesis was tested by thematic analysis.

Facilitators employed by participants to supplement their cessation attempts

Since the study did not provide nicotine replacement therapy (NRT) to participants to assist in combating their cravings, withdrawals, and sustainment of their cessation attempts, some participants added their own facilitators to supplement and implement the study's group behavioural counselling strategies. Themes included:

1. Oral stimulation

Most participants reported that they noted that as long as their mouths were busy, then they did not have cravings. Strategies used included eating: raw eggs, sweets, gum, and bananas. Some participants reported that raw eggs alleviated feelings of withdrawals and managed headaches. Some participants realized that chewing gum or eating tropical (e.g. mint flavoured) sweets delayed cravings for smoking.

"My father stopped smoking by swallowing 2 raw eggs in the morning. When I started my quit attempt, and was struggling, I thought to try his way. The first day it was difficult, but after a while I got used to it, and I realized I had reduced my smoking drastically. So, I shared with some of our group members." (26-year-old, male)

"The cigarettes I smoke have menthol, and the tropical sweets or chewing gum give me a similar taste, and I believe confuses my mind that am smoking." (40-year-old, female)

2. Spousal and friend support

Participants reported sharing what they were learning during the intervention sessions with their spouses, families, and friends. Strategies included: throwing away cigarettes and lighters found in the house, not smoking in the home, and not being allowed to smoke in the presence of family and friends. Some participants made a pact with their spouses to throw away any of their cigarettes if they found them. Unfortunately, all participants who tried this strategy relapsed, including trying to smoke cigarettes while they were wet.

"My wife would wait for me to come home and change, search through my clothes and throw away the cigarettes in water. First day she searched the whole house and threw away all of my cigarettes." (39-year-old, male)

Some participants decided to stop sharing their cigarettes with friends and to stop borrowing cigarettes. This helped them smoke only the cigarettes that they had bought, and most participants reported buying single sticks to aid in reduction of amounts.

"I only buy one cigarette and smoke it in bits throughout the day. I have stopped taking puffs from others, and I also don't give puffs. I therefore smoke less amounts." (28-year-old, female)

Subthemes included cutting down, whereas some participants reported fear of quitting without medication due to their previous quit attempts.

"I don't think just stopping completely will be possible for me. Since the program is for some months, I will focus on reducing at least 2 sticks every week until I stop completely." (33-year-old, female)

Additional strategies developed by study participants for tobacco cessation

Two groups started their own "table banking" groups with the transport token they used to receive during their session days. Table banking is group-based funding strategy in which members save and borrow immediately during their meeting times to ensure all group members attended the counselling sessions so that each can receive his/her token for their contribution. With this initiative, other patients who had not been part of the study started requesting to be part of the study. These 2 groups thus worked to spread news that there were cessation sessions available at the hospital.

During the discussions, the participants reported that they would have preferred more frequent group behavioural intervention sessions, than the bi-weekly meetings and as such, they created WhatsApp or short message service groups. According to them, the idea that they were going to be asked about their tobacco use experiences, made them work harder at quitting attempts. The group meetings also worked to encourage them to continue making quit attempts, as it became a competition on who was making the most progress.

Another observation was that the participants in the different groups started checking on each other, and working as support groups. They formed a WhatsApp group that they used to remind each other of the meeting dates. Unfortunately, there are participants who were unable to afford internet and could not participate in the group. This led to reduction of the group interactions, but enhanced short message

communication, as this was cheaper. There were participants that used their parents/spouses' phones as they did not have their own, and it was noted that the spouses starting calling to check if the participants had attended the group meetings. If a participant was late in attending, or missed a session, they would call each other, and the times that 2 members became pregnant while in the study, they kept reminding each other on the impact of the tobacco use on the unborn children.

CHAPTER 5: DISCUSSION

Summary of Results

Using a Randomised clinical trial design, the study sought to determine the efficacy and safety of a group tobacco cessation behavioural intervention among tobacco using patients with mental illnesses on tobacco cessation at 26 week follow-up, and to evaluate the effect of a group tobacco cessation behavioural intervention on health-related quality of life of patients with mental illnesses.

The main study findings include: 1) Participants allocated to the intervention group reported a higher cessation rate and lower number of cigarettes or kuber smoked compared with the control group over the study period; 2)The unadjusted results showed that participants in the intervention group at any point during the study period were almost 14 times more likely to reduce smoking than participants in the control group, though there were a small number of events driving this finding; 3) Intervention group participants reported higher HRQoL OR scores in all domains at the end of the study compared with control group participants; 4) Qualitative results identified themes under *barriers to quitting tobacco use* including: peer influence, withdrawal symptoms, fear of complete cessation, other substance use and end-month disputes; and 5) Themes that were *facilitators* employed by participants to supplement their cessation attempts included: oral stimulation and spousal and friends support.

Tobacco use kills nearly 1 out of every 2 long-term users with most deaths due to non-communicable diseases.[136] A 2014 epidemiologic study in California found that half of those who had been hospitalized for schizophrenia, bipolar disorder, or major depressive disorder died due to diseases linked to tobacco use.[137]

Quitting smoking has been shown to increase improvements in mental health, including reductions in depression, anxiety, and PTSD symptoms. A 2014 meta-analysis of 26 tobacco intervention studies found that smoking cessation was significantly associated with decreased anxiety, depression, and stress and improvements in overall mood and quality of life.[138, 139,140]

While there is a growing appreciation and prioritization among tobacco researchers of the high smoking prevalence among those with mental illness, [141] the lack of decline suggests that efforts at the general population level are not effectively addressing tobacco-related disparities.[142]

Socio-Demographic Characteristics

Sex

Most (87%) participants were male, which is similar to the global prevalence whereby the prevalence of smoking is higher for men (40% in 2006) than for women (nearly 9% in 2006), and males account for 80% of all smokers (nearly 1 billion).[143] This differs from the general Kenyan population, where ratio of males to females is almost similar 1:1.02.[144] However, this is similar to previous studies that have shown the number of male patients at Mathari Referral hospital to be slightly higher (63%) compared to the number of females.[145]

During recruitment, only 1 female ward had patients attending outpatient clinic and out of it, none reported tobacco use. Females who joined the study were recruited at the CSAT and MAT outpatient clinics. Studies on gender-specific multivariate logistic regression models have shown that there is evidence of a gender interaction with factors leading to mental illnesses. [146] This gender difference was however not found to be significant and did not have any impact on the outcomes.

Age

Mean age of participants was 35 years, with the youngest participants being 18 years, while the oldest was 73 years. This finding is similar to those of a study by Ndetei et al., (2008) [145] which showed that majority of patients at Mathari referral hospital were aged between 26 years and 40 years.

Education

Africa's current primary school enrolment rate is above 80% on average, with the continent recording some of the biggest increases in elementary school enrolment globally in the last few decades, according to the United Nations Educational, Scientific and Cultural Organization (UNESCO).[147]

Education studies have shown a significant relationship between the prevalence of common mental disorders and low educational levels.[148]
The level of education was well distributed with about one-third having studied and stopped at primary school, almost half having stopped at secondary school, and another third having completed tertiary school. This is similar to a study by Ndetei et al., (2008) which showed that up to 40% of the patients at Mathari had completed secondary school.[145]

Only 2% of study participants had not attained any formal education. This is in line with the general population statistics, where the number of people who have never gone to school is low and decreasing.[144] The level of baseline education did not influence the overall effect of the intervention after multivariable adjustment. We did not test for a formal interaction by baseline education due to a low number of events and likelihood that any interaction observed would likely be driven by chance. This contrasts with other results that demonstrate differences in smoking cessation

across different educational groups, [149] but prior research has not reported an interaction of effect with group therapy on cessation by baseline education.

Employment

A large percentage of the study participants were either unemployed or self-employed, and only one-quarter of participants were employed. This is similar to studies that have shown an even higher incidence of unemployment in patients exposed to mental illness.[150] Unemployed persons and those who fail to gain employment have more depressive symptoms than individuals who find a job.[151]

Employment status was found not to be statistically significantly to tobacco use. This was in contrast to a study by Kleinman in 2003, whereby he observed that persons with mental illness were more likely have a lower educational level, which prevented access to most professional jobs, increased vulnerability and insecurity, and contributed to a persistently low social capital.[148]

Mental health disorders

Most participants were being managed for substance use disorder, with almost one-quarter being managed for major depression, fewer for schizophrenia and bipolar disorder, and only 1% being managed for anxiety disorders. This is similar to studies which have shown that the prevalence of smoking among persons with alcohol use disorders is well above 80% and that poly drug users also smoke a lot.[152, 153] Investigators have reported a relationship between depression and smoking.[154] A study by Ndetei et al.,(2008) found that the most common mental illnesses at Mathari Referral Hospital were depression and schizophrenia, which contrasts to the population recruited into this study.[145]

H1. Group tobacco cessation behavioural interventions increases quit attempts among patients with mental illness

The null hypothesis was rejected in the hypothesised positive association between group tobacco cessation behavioural interventions and increase in quit.

Reduction in Number of Cigarettes Smoked

Study participants in the intervention group reported higher rates of reduction in amounts smoked compared to those in the control group. This reduction was statistically significant. The unadjusted results showed that participants in the intervention group at any point during the study period were almost 14 times more likely to reduce smoking than participants in the control group.

The study encouraged frequent attempts to quit, and the participants' efforts and number of cigarettes reduced were documented during each meeting. The participants were not told to stop tobacco use immediately as the study was not offering nicotine replacement therapies. Smoking reduction could decrease the severity of withdrawal and cravings when smokers abstain altogether. Indeed, withdrawal effects and cravings are the main barriers to achieving cessation and contributing to relapse.[155] In the context of smoking, gradually reducing the number of daily cigarettes may induce intermittent reinforcement, offering encouragement to and increasing the likelihood of quitting altogether, and therefore potentially increase self-efficacy. Increases in self efficacy are thought to heighten the likelihood that a final goal – in this case cessation – will be achieved.[156]

Study participants were followed up for 6 months. Being a vulnerable population, the inability for most participants to achieve complete cessation could have meant that they needed a longer period or more frequent dose of the group behavioural intervention than the general population. For example, 45% of

intervention group participants were smoking less than 2 cigarettes per day, and a longer intervention may have increased the cessation rate though perhaps at a cost of a higher lost to follow-up rate. This potential value of longer duration of follow-up or more intensive weekly sessions was supported by participants who requested continuity of the follow up, but this was not feasible. During the focus group discussions, the need for more regular interactions among the participants was highlighted. Support groups that would avail these regular interactions is an area that could be considered when integrating tobacco cessation programs. Fiore et al., (2008) in the Clinical guidelines for tobacco cessation advocates for more intensive interventions as well as combination with pharmacotherapy to improve cessation outcomes. [157]

Biochemically Verified Quits

The intervention group had 3 (9.1%) successful quits made that were biochemically verified, while the control group had none (0%). While these results were not statistically significant, there was limited power to detect a potential difference. Whether a larger trial with more participants may have demonstrated a difference is uncertain but is plausible. However, the high loss to follow-up rate suggests that strategies to promote retention in the intervention will likely be useful to maximize the intervention's effectiveness.

Quitting smoking is difficult, with only 3–5% of those who quit without assistance, and fewer than 10% of all smokers achieving long-term abstinence, and often only after many unsuccessful quit attempts.[158]

The study by Baker et al., (2006) showed that maintaining cessation among this population is very difficult. The study found that treatment worked for a minority

of patients. Among those who completed all treatment sessions, point-prevalence abstinence rates were 30.0% at 3 months and 18.6% at both 6 and 12 months. Continuous abstinence rates at 12 months were 0.7% in the comparison group, and 3.4% in the treatment group, with a maximum of 7.1% in those who attended all sessions. A need exists for finding new cessation treatments that will benefit people for whom the current treatments have poor outcomes.[159]

H2. There is an association between tobacco use changes to the changes in health-related quality of life among patients with mental illness.

The hypothesised positive association between tobacco cessation and improvement in quality of life was partly confirmed.

Health-related quality of life versus cessation outcomes

Intervention group participants reported higher HRQoL scores in 2 main domains at the end of the study compared with control group participants. The greatest improvement was noted in the environmental domain (34.7% vs 8.3%) and physical domain (30.6% vs 10.4%). The physical domain as defined in the WHOQOL-BREF guideline, deals with the functioning of the body in areas such as energy and fatigue.

Systematic reviews on impact of smoking cessation, particularly on major non-communicable, chronic diseases, show that it is highly beneficial. In a summary by Lee et al., (1993) a substantial reduction in smoking improves several cardiovascular risk factors and respiratory symptoms.[160] It has also been documented that stopping tobacco use leads to improvements in bodily functions from as soon as 20 minutes.[177] Lack of chest pain and having energy throughout the

day would denote improvement in quality of life. A subsequent study showed evidence that smoking reduction decreased fatal and non-fatal cardiovascular disease even rates, reporting a hazard ratio (HR) of “reducers” over “maintainers” of 0.77 (95 % confidence interval (CI), 0.66–0.94).[161]

According to the WHOQOL BREF guideline, the environmental domain focuses on areas such as the environment, (whether one feels safe, access to healthcare, work satisfaction, and transport). The finding on improvement in the environmental domain was also due to a confounding variable- reimbursement. Participants having some reimbursement for the extra time spent in the hospital, meant that they could afford transport for their next appointment, thereby ensuring access to healthcare. Having improvement in the physical domain could have impacted on the improvement in the environmental domain as well. This is because when one is not feeling physically sick, confidence in one self may be enhanced. Also, it becomes easier for one to have access to healthcare as walking is no longer a problem, and he can enjoy his work.

Similar to our study, a tobacco cessation study (SCMITAR) among persons with mental illness, HRQoL was measured using the SF-12 questionnaire, which showed improvement in physical health in the intervention group at 6 months, but this difference was not evident at 12 months. For the mental health domain outcome, there was no difference between the groups at 6 or 12 months.[162] It was however noted that in the SCMITAR study, the participants were all male, with median age 47 years (IQR 36-55), with high nicotine dependence (mean 24 cigarettes per day [SD 13]), and the most common severe mental disorders were schizophrenia or other psychotic illness (65%), bipolar disorder (22%), and schizoaffective disorder (13%); which are different from our study population. The intervention group

sessions were also shorter at 39 minutes and the participants received cessation medication.[162]

H3. Patients experience different barriers in their quit attempts.

Group therapy has been shown to offer added value by fostering peer support and is likely to be more cost-effective than individual counseling.[163] Group CBT-based programs of approximately 8-10 individuals that meet weekly for 7-10 weeks have been shown to have the most successful quit rates for the mental health population, compared to individual counselling.[96] Most of the studies however were noted to include NRTs and other cessation pharmacotherapies in their intervention; this is one of the main difference between our studies and most group tobacco cessation interventions focusing on this group.

The current study found some barriers experienced by the participants in their quit attempts to include: 1) peer-influence, 2) withdrawal symptoms, including headaches and cravings, 3) fear of complete cessation, 4) other substance use, particularly methadone, cannabis and alcohol, 5) end of month disputes, when they were expected to make rent or similar payments, and 6) boredom, including when they were not at the hospital or working.

Most barriers experienced by participants have been reported among the general population but some facilitators, like swallowing raw eggs, were less common. This could have been borrowed from some of the practices used by alcohol consumers where raw eggs are used to cure hangovers, as marketed online.[164] Peer pressure as a barrier was expected, as it affects most people attempting cessation.[165] This population that was meeting regularly may have been more susceptible to peer pressure, but this is speculative. This is because pairing smokers together to make the quit attempt improves success rates.[165] Use of other

substances of abuse was also noted to be a barrier. Prevalence of other substance use among this population has been documented, and it being a barrier was anticipated because people with mental illness may use other substances to block their psychotic episodes, increase their mood, or give them a euphoric effect, particularly when feeling depressed.[166]

Similar to the current study results, Twyman et al. (2014) noted that barriers to quitting smoking endorsed over multiple studies included smoking for stress management, boredom, social acceptability of smoking, and lack of support to quit and access to quit resources.[20] Findings in this study showed that participants complained that one of the barriers they experienced was boredom. This has been shown to be similar with the general population.[20]

Just as the current study found that cannabis and methadone were barriers to cessation among this population, research supports this finding. Patients with substance use disorders for other substances smoke more (80% to 98%) and are more vulnerable to the effects of smoking than the general population (16% to 30%) [167] Cannabis is most commonly smoked with tobacco, and people with psychotic illness smoke more tobacco than the general population.[168] This might explain why it was difficult for the participants to quit cannabis as well as tobacco use. Most (93%) methadone users on outpatient treatment in the United Kingdom smoke cigarettes.[169] Methadone has been shown to increase cigarette smoking in a dose-dependent manner, whereas smoking/nicotine has been shown to increase methadone self-administration and reinforcing properties.[170] This supports the findings from the participants.

Smoking to reduce stress was a frequently reported barrier, particularly towards the end of the month and largely due to financial constraints. Studies have

shown that smokers typically demonstrate higher levels of stress and low mood than non-smokers and ex-smokers. Unemployment, financial stress, and poverty, which are stressors associated with vulnerable groups, may compound stress levels.[171]

The current study highlighted that key barriers faced by people who have mental illness and use tobacco are similar to those faced by the general population.[20] The participants in the study worried about withdrawal symptoms, particularly headaches and cravings. Most worried about not being able to concentrate and therefore being tobacco free was counterproductive at that time. These withdrawal challenges were also noted in a study by Piper et al., (2012). They noted that withdrawal symptoms particularly cravings made people resume tobacco use.[173]

There are those whose concerns were losing friends, as those are the ones with whom they were hanging out and those who understood them and their concerns. A study by the International Tobacco Control (ITC) Project Four Country Survey, a longitudinal cohort survey of nationally representative samples of adult smokers in Australia, Canada, United Kingdom, and United States (N=6,321), found that smokers who inhabit social contexts with a greater number of smokers may be less likely to successfully quit. According to the study, quitting may be particularly unlikely among smokers who do not experience a loss in the number of smokers in their social context. [174] This study confirmed the reports by the participants and also explained the progress in the reduction in amounts of tobacco used.

Most worried that since they had already used tobacco for years, their health might already be too impaired for help, and were fatalistic that quitting tobacco would not alter their health status or trajectory. Some did not want to quit because they felt tobacco made them feel better and reduced their psychiatric symptoms, especially

during ‘low’ times. Most participants who were worried about alleviating their psychotic symptoms reported wanting to reduce smoking, but not quit completely. Peer reviewed tobacco cessation articles focusing on patients with mental illness, between years 1990 to 2008, showed that patients with mental health conditions may smoke as a form of self-medication. It also highlighted that several of the studies showed that some symptoms of psychiatric disorders may be exacerbated by nicotine withdrawal. Therefore, attempts to quit smoking posed additional problems to patients with mental health problems. Preliminary evidence suggested that more flexible, open-ended, combination approaches of pharmacotherapy and counselling may be more successful. This review confirmed some of the worries that were hampering successful cessation by the participants.[175]

H4. Patients involved in group tobacco cessation behavioural interventions incorporate their own facilitators during their quit attempts.

To manage the above barriers, participants incorporated facilitators that were not part of the group behavioural sessions, including: 1) oral stimulation, including swallowing raw eggs, chewing sweets with mint or chewing gum, and 2) spousal and friend support.

In a Central America study that explored barriers and facilitators to a smoking cessation intervention, former smokers reported facilitators to quitting including: 1) seeing the health consequences of smoking among their patients, 2) personal and family health concerns, and 3) receiving support from family. These are similar to the current study, where spousal and friend support were seen as important facilitators.[176]

In a study by Cocks et al., (2019), the relevance and value of shared lived experiences in challenging stigma, marginalization, and low expectations

demonstrates the contribution that peer support can offer to support smoking cessation.[177] Incorporating a recovery orientation approach to smoking cessation treatment highlights the value of peer support. This requires the intentional use of lived experience in the support of others, and recognition that concepts like connectedness, hope, identity, meaning, and empowerment have an important role in supporting the efforts of people living with severe mental illness to quit. [178,179]

Similar to a finding on our study on the need for oral stimulation, an article on tobacco cessation by the Mayo Clinic,[180] suggest that one can "chew on it" to reduce cravings. This program suggests that one should give the mouth something to do to fight tobacco cravings, such as chewing on sugarless gum, or eating crunchy foods like low-sugar candy, raw carrots, celery, nuts or sunflower seeds.

Strengths

The study has key strengths, including being conducted in participants' usual environments, as well as during outpatient clinic follow-up days, which signals that this intervention can be naturally implemented. Second, the study focused on strategies that were readily available and did not have significant direct costs for participants in terms of attending group therapy. Third, the study was performed in a novel setting in a high-risk, vulnerable group of tobacco users with concomitant mental illness, highlighting the clinical significance of the intervention.

Limitations

The current study also had some important limitations, which may influence the certainty of the findings.

Ascertainment bias

Participants self-reported their quit attempts and reduction in amount smoked during every group meeting. Systematic reviews have indicated that self-reports of smoking status are mostly accurate unless the participants fear loss of particular benefits if they do not quit.[181] In self-initiated interventions such as the current study, participants did not suffer nor lost (nor gained) benefits as a result of their purported abstinence; therefore, the incentive for inaccurate self-reporting was minimized.[182] To reduce the risk of ascertainment bias, biochemical verification was conducted on participants who reported complete cessation.

Attention bias

By design, the intervention group met more frequently compared to the control group, which may partially explain the study results. Participants may have benefited from the study intervention but may have also been susceptible to the Hawthorne's effect, wherein their behaviour changed because of the process of observing the behavior.[183] In the study we sought to minimize the effect of this by integrating into usual clinical practice days. We also held intervention sessions on different days than the control groups' clinical practice days, which reduced the risk of contamination. It is arguable but seems unlikely that control participants might have been motivated to quit tobacco if they perceived that the intervention group was receiving 'special treatment'.

Attrition bias

We decided to treat all participants who were lost to follow up as smokers in the intention to treat analysis. This conservative approach is the typical method of handling missing data in smoking cessation trials.[184] The research team tried to contact all participants who were missing before the group meetings began. When a

participant had failed to attend meetings for 3 consecutive times, then they were counted to have dropped out (lost to follow-up).

Generalizability

The generalizability of this study is limited because of the relatively small sample size among participants at a single referral centre in an urban setting. Whether similar results could be observed in less-resourced or more remote settings or with co-interventions is uncertain but important for understanding how tobacco cessation interventions can be scaled to better match the current disease burden. Efforts such as team triangulation during data collection and analysis were used to improve the rigor and creditability of the study.

RECOMMENDATIONS AND CONCLUSIONS

Recommendations

We recommend that future research include NRT as well as medication adherence as covariates when investigating efficacy of group tobacco cessation behavioural interventions. There is need for support groups for this population who are accessing tobacco cessation support.

Study Conclusions

1. This intervention is feasible for the mentally ill population with tobacco use dependence particularly in low and middle income countries.
2. This study showed that persons with mental illness are willing to quit tobacco use and can successfully reduce the number of cigarettes used through a group behavioural intervention, even without cessation pharmacotherapies.
3. The study also highlighted that tobacco cessation can improve health-related quality of life in the physical and environmental domains.

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APPENDICES

APPENDIX 1

CONSENT EXPLANATION and CONSENT FORM

I am Yvonne Olando, a PhD Student in clinical psychology, at the University of Nairobi. I am doing research on 'Effectiveness of group tobacco cessation intervention among mentally ill tobacco users seeking outpatient services'. I am going to give you information and invite you to be part of this research.

Purpose of the research

Tobacco use is common among patients with mental health disorders. Tobacco use also leads to adverse health effects to these patients; cessation/quitting will therefore lead to better health. Getting these data will help the healthcare Center's as a whole put better programs or add the information to their programs to enable reduction in the number of relapses, if not stop it completely.

This research will involve administration of some questionnaires which will be collected immediately after they have been filled.

I am inviting all adults who have been using tobacco products for the past six months and would like to quit, participating in this study.

Your participation in this research is entirely voluntary. Whether you choose to participate or not, all the services you receive at this healthcare facility will continue and nothing will change. If there is anything you are concerned about or that is bothering you about the research please talk to me or one of the other staff members.

Risks

No serious risks are envisioned. However, I will follow you closely and keep track of any unwanted effects or any emotions to ensure you are properly taken care of.

Benefits

If you participate in this research, you will have the following benefits: You will get support in your tobacco use quit attempts, find out how to cope with your triggers and also evaluate your high-risk situations while coming up with a relapse prevention plan.

Confidentiality

We will not be sharing the identity of those participating in the research. Information about you that will be collected during the research will be put away and no-one but the researcher will be able to see it. Any information about you will have a number on it instead of your name. Only the researcher will know what your number.

Sharing the Results

Confidential information will not be shared. At the end of the study, the findings will be published in journals and presented in conferences.

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands what the research entails.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Explanation has been provided to the participant.

I voluntarily agree to participate in this research study.

Name of Participant: _____

Signature: _____

Date: _____

Name of Researcher/person taking the consent: **Yvonne Olando**

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

APPENDIX 1B

MAELEZO YA MARIDHIANO

Jina langu naitwa Yvonne Olando, mwanafunzi ninayesoma shahada ya uzamifu katika somo la saikologia katika Chuo Kikuu Cha Nairobi. Ninafanya utafiti juu ya "mikakati yenye ufanisi katika kuthibiti makundi ya walioathirika kiakili kutokana na matumizi ya tumbaku wanaotafuta usaidizi wa huduma za nje ya hospitali." Nitakupatia habari kuhusu utafiti huu na pia nikualike kuwa sehemu yake.

Kususi la Utafiti

Utumiaji wa tumbaku huonekana sana miongoni mwa wagonjwa wenye matatizo ya kiakili.

Utumiaji wa tumbaku pia unachangia madhara mabaya ya kiafya kwa wagonjwa hawa, kwa hivyo kuacha kutumia tumbaku kutachangia afya bora. Kupata twakimu hizi kutasaidia kituo cha afya kwa ujumla kuweka mipango bora zaidi ama kuongeza maelezo haya kwa mipango yao ili kupunguza visa vya kurudia matumizi ya tumbaku kama si kukomesha matumizi kabisa. Utafiti huu utahusisha kupeanwa kwa dodoso, ambazo zitachukuliwa punde tu baada ya kumalizwa kujazwa.

Ninaalika watu wazima wote ambao wamekuwa wakitumia tumbaku kwa miezi misita iliyopita na wangependa kuacha, kuhusika na utafiti huu.

Kuhusika kwako kwa utafiti huu ni kwa hiari. Kama utachagua kuhusika au kutohusika, huduma zote unazozipata katika kitui hiki cha afya zitaendelea na hakuna kitu kitabadilika. Kama una wasiwasi na jambo lolote ama unasumbuliwa na kitu chochote kuhusu utafiti huu tafadhali zungumza na mimi au mmoja wa wafanyikazi wengine.

Hatari

Hakuna hatari kubwa zinatarajiwa, hata hivyo nitakuangalia kwa makini na kufuatilia madhara au hisia zozote zisizotakikana ili kuhakikisha unashuhulikiwa vyema.

Faida

Kama utashiriki katika utafiti huu, utapata faida zifuatazo: utapata usaidizi katika harakati zako za kuacha matumizi ya tumbaku, utajua jinsi ya kukabiliana na

vichochezi vyako na pia kupima hali zako za hatari na kupata mpango wa kuzuia kurudia matumizi ya tumbaku.

Usiri

Hatutashiriki habari kuhusu watu watakao shiriki katika utafiti huu. Habari zozote kukuhusu zitakazokusanywa wakati wa utafiti zitawekwa kando na hakuna mtu atakayeweza kuziona isipokuwa mtafiti.

Habari zozote kukuhusu zitakuwa zimewekewa namba badala ya jina lako. Ni utafiti pekee atajua namba hiyo.

Kushiriki matokeo

Habari za siri hazitatolewa. Baada ya utafiti huu, matokeo yatatolewa kwa machapisho na pia kwa makongamano.

Kauli ya Mtafiti/ Mtu anayeridhia

Nimesoma kwa usahihi karatasi ya maelezo kwa anayetarajiwa kuhusika na utafiti, na nimehakikisha kadri ya uwezo wangu kuwa muhusika ameelewa utafiti unahusiana na nini.

Nathibitisha kuwa muhusika alipewa nafasi ya kuuliza maswali kuhusu utafiti huu, na maswali yote yaliyoulizwa na muhusika yamejibiwa kisawasawa kadri ya uwezo wangu. Nathibitisha kuwa muhusika hajalazimishwa kuridhia jambo hili na ametoa ridhia kihuru na kwa hiari yake.

Nakala ya maelezo ya ridhaa hii imepeanwa kwa muhusika.

Nimekubali kushiriki katika utafiti huu kwa hiari yangu.

Jina la Mtu anyeridhia: _____

Sahihi ya mtafit:_____

Tarehe:_____

Mtu anayechukua ridhaa: **Yvonne Olando**

Jina la mtafiti/Mtu anayechukua ridhaa_____

Tarehe: _____

APPENDIX 2

FAGERSTROM TEST

Fagerstrom Test for Nicotine Dependence

Take this test and find out your level of dependence on nicotine. Is smoking “just a habit” or are you addicted?

1. How soon after you wake up do you smoke your first cigarette? ♦ After 60 minutes (0) ♦ 31-60 minutes (1) ♦ 6-30 minutes (2) ♦ Within 5 minutes (3)

2. Do you find it difficult to refrain from smoking in places where it is forbidden? ♦ No (0) ♦ Yes (1)

3. Which cigarette would you hate most to give up? ♦The first in the morning (1) ♦ Any other (0)

4. How many cigarettes per day do you smoke? ♦ 10 or less (0) ♦ 11-20 (1) ♦ 21-30 (2) ♦ 31 or more (3)

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day? ♦ No (0) ♦ Yes (1)

6. Do you smoke even if you are so ill that you are in bed most of the day? ♦ No (0) ♦ Yes (1)

Your score was: . Your level of dependence on nicotine is: .

SCORING

0-2 Very low dependence

3-4 Low dependence

5 Medium dependence

6-7 High dependence

8-10 Very high dependence

[Scores under 5: “Your level of nicotine dependence is still low. You should act now before your level of dependence increases. “

[Score of 5: “Your level of nicotine dependence is moderate. If you don’t quit soon, your level of dependence on nicotine will increase until you may be seriously addicted. Act now to end your dependence on nicotine.”

[Score over 7: “Your level of dependence is high. You aren’t in control of your smoking – it is in control of you! When you make the decision to quit, you may want to talk with your doctor about nicotine replacement therapy or other medications to help you break your addiction.”

APPENDIX 2B

KIPIMO CHA FAGERSTROM

Kipimo cha Fagerstrom cha utegemeaji wa Nikotini

Chukua kipimo hichi ili kujua utegemeaji wako wa nikotini. Je kuvuta sigara ni tabia tu ama wewe ni mraibu?

1. Baada ya kuamka, unachukua mda gani kabla kuvuta sigara yako ya kwanza?♦ Baada ya dakika 60 (0) ♦ 31-60 minutes Kati ya dakika 30 na 60(1) ♦ Kati ya dakika 6 na 30(2) ♦ Ndani ya dakika tano minutes (3)

2. Je unaona vigumu kutovuta sigara sehemu ambazo uvutaji wa sigara hauruhusiwi?♦ Hapana (0) ♦ Ndio(1)

3. Ni sigara gani unachukia sana kuacha?♦Ya kwanza asubui (1) ♦ Nyengine yeyote (0)

4. Unavuta sigara ngapi kwa siku?♦ 10 au chini ya kumi (0) ♦ 11-20 (1) ♦ 21-30 (2) ♦ 31 ama zaidi (3)

5. Je unavuta sana masaa ya kwanza baada ya kuamka kuliko siku nzima?♦ Hapana(0) ♦ Ndio (1)

6. Je unavuta sigara hata wakati ukiwa mgonjwa na uko kitandani karibu siku yote?♦ Hapana (0) ♦ Ndio(1)

Alama ulizopata: .

Utegemeaji wako wa nikotini ni: .

0-2 Unategemea kiwango cha nchini sana 6-7 Unategemea kiwango cha juu

3-4 Unategemea kiwango cha chini

8-10 Unategemea kiwango cha juu sana

5 Unategemea kiwango cha wastani

[Alama chini ya 5: " Kiwango chako cha kutegemea nikotini bado ni kidogo. Fanya kitu sasa kabla kiwango chako cha utegemeaji kiongezeke."

[Alama 5: "Utegemeaji wako wa nikotini uko kiwango cha wastani. Kama hautaacha karibuni, kiwango chako cha utegemeaji kitaongezeka mpaka mraibu haswa."

[Alama zaidi ya 7: "Kiwango chako cha utegemeaji kiko juu. Haujathibiti uvutaji-uvutaji umekuthibiti! Utakapofanya uamuzi wa kuacha, unaweza lazimika kuzungumza na dakatari wako kuhusu tiba ya mbadala wa nikotini ama madawa mengine ya kukusaidia kuvunja uraibu wako"

APPENDIX 3

SOCIO -DEMOGRAPHIC QUESTIONNAIRE (SDQ)

Instructions: Where applicable, circle the correct option. Do not write your name on the questionnaire.

1. Participant admission no/Client no._____
2. Age_____
3. Gender:
    a) Male
    b) Female
4. Place of residence:
   County_____
   Estate_____
5. Level of Education:
    a) None
    b) Primary
    c) Secondary
    d) College/Diploma/Certificate
    e) University
6. Occupation
    a) Student
    b) Unemployed
    c) Employed
    d) Self employed
7. How do you feel about your general health?
    a) Good
    b) Fair
    c) Poor
8. Quality of health using the SF-12 score?

9. Mental health condition being managed for:
    a) Substance abuse

b) Major depression
c) Bipolar
d) Schizophrenia
e) Other_____

10. Which tobacco product do you use?
    a) Cigarrattes?
    b) Mbaku/Kuber?
    c) Shisha
    d) Other_____
11. Average number of tobacco/ cigarettes used/smoked per day.
    a) 10 or less
    b) 11-20
    c) 21-30
    d) 31 or more
12. How many years have you been using tobacco products?

13. At what age did you start tobacco use?

14. Nicotine dependency score using the Fagerstrom test?

15. Would you like to quit tobacco use?
    a) Yes
    b) No
    c) Not sure
16. Do you use any other substance of abuse (Alcohol, Bhang, Miraa etc)?
    a) Yes
    b) No

    If Yes,

    - Which one?
    - How long have you been using the substance?

APPENDIX 3B

DODOSO LA IDADI KATIKA JAMII

Maagizo: Pale inapohusika, tafadhali chora mviringo chaguo lililo sawa. Usiandike jina lako kwa dodoso hili.

1. Namba ya uandikishaji ya muhusika/ Namba ya mteja_____
2. Umri_____
3. Jinsia:
    a) Mume
    b) Mke
4. Mahali unapoishi:

Kaunti_____

Mtaa_____

5. Kiwango cha Elimu:
    a) Hakuna
    b) Msingi
    c) Upili
    d) Chuo/Stashahada/Cheti
    e) Chuo Kikuu
6. Kazi
    a) Mwanafunzi
    b) Sina Kazi
    c) Nimeajiriwa
    d) Nimejiajiri
7. Unahisije kuhusu afya yako kwa ujumla
    a) Vizuri
    b) Wastani
    c) Vibaya
8. Ubora wa afya ukitumia alama za SF-12?
9. Hali ya afya ya kiakili unayoangaliwa?

a) Utumiaji wa madawa ya kulevya
b) Major depression Huzuni kubwa
c) Bipolar Nusu kwa nusu
d) Schizophrenia Dhiki
e) Other_Mengine_____

10. Unatumia bidhaa gani za tumbaku
    a) Sigara?
    b) Kuber?
    c) Shisha
    d) Nyengine_____
11. Unatumia kama sigara ngapi kwa siku?
    a) 10 au chini ya 10
    b) 11-20
    c) 21-30
    d) 31 au zaidi ya 31
12. Umetuma bidhaa za tumbaku kwa miaka mingapi?

13. Ulianza kutumia bidhaa za tumbaku ukiwa umri gani?

14. Kwa kutumia kipimo cha Fagerstrom, kiwango chako cha kutegemea tumbaku ni gani?

15. Je ungependa kuacha kutumia tumbaku?
    a) Ndio
    b) La
    c) Sina hakika
16. Je unatumia madawa ya kulevya aina nyengine (Pombe, bangi,miraa, n.k)?
    a) Ndio
    b) La

    Kama ndio,

    - Gani?
    - Umetuma kitu hicho kwa mda gani?

APPENDIX 4

WHOQOL-BREF

The following questions ask how you feel about your quality of life. I will read out each question to you, along with the response options. Please choose the answer that appears most appropriate. If you are unsure about which response to give to a question, the first response you think of is often the best one (The numbers after responses indicates the scores of the responses).

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life in the last four weeks (The overall quality of life and general health facet).

1. How would you rate your quality of life?

Very poor: 1

Poor: 2

Neither poor nor good: 3

Good: 4

Very good: 5

2. How satisfied are you with your health?

Very dissatisfied: 1

Dissatisfied: 2

Neither satisfied nor dissatisfied: 3

Satisfied: 4

Very satisfied: 5

The following questions ask about how much you have experienced certain things in the last four weeks.

3. To what extent do you feel that physical pain prevents you from doing what you need to do?

Not at all: 5

A little: 4

A moderate amount: 3

Very much: 2

An extreme amount: 1

4. How much do you need any medical treatment to function in your daily life?
Not at all: 5
A little: 4
A moderate amount: 3
Very much: 2
An extreme amount: 1

5. How much do you enjoy life?
Not at all: 5
A little: 4
A moderate amount: 3
Very much: 2
An extreme amount: 1

6. To what extent do you feel your life to be meaningful?
Not at all: 5
A little: 4
A moderate amount: 3
Very much: 2
An extreme amount: 1

7. How well are you able to concentrate?
Not at all: 1
A little: 2
A moderate amount: 3
Very much: 4
Extremely: 5

8. How safe do you feel in your daily life?
Not at all: 1
A little: 2
A moderate amount: 3

Very much: 4
Extremely: 5

9. How healthy is your physical environment?
Not at all: 1
A little: 2
A moderate amount: 3
Very much: 4
Extremely: 5

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

10. Do you have enough energy for everyday life?
Not at all: 1
A little: 2
Moderately: 3
Mostly: 4
Completely: 5

11. Are you able to accept your bodily appearance?
Not at all: 1
A little: 2
Moderately: 3
Mostly: 4
Completely: 5

12. Have you enough money to meet your needs?
Not at all: 1
A little: 2
Moderately: 3
Mostly: 4
Completely: 5

13. How available to you is the information that you need in your day-to-day life?

Not at all: 1

A little: 2

Moderately: 3

Mostly: 4

Completely: 5

14. To what extent do you have the opportunity for leisure activities?

Not at all: 1

A little: 2

Moderately: 3

Mostly: 4

Completely: 5

15. How well are you able to get around?

Very poor: 1

Poor: 2

Neither poor nor good: 3

Good: 4

Very good: 5

16. How satisfied are you with your sleep?

Very dissatisfied: 1

Dissatisfied: 2

Neither satisfied nor dissatisfied: 3

Satisfied: 4

Very satisfied: 5

17. How satisfied are you with your ability to perform your daily living activities?

Very dissatisfied: 1

Dissatisfied: 2

Neither satisfied nor dissatisfied: 3

Satisfied: 4

Very satisfied: 5

18. How satisfied are you with your capacity for work?

Very dissatisfied: 1

Dissatisfied: 2

Neither satisfied nor dissatisfied: 3

Satisfied: 4

Very satisfied: 5

19. How satisfied are you with yourself?

Very dissatisfied: 1

Dissatisfied: 2

Neither satisfied nor dissatisfied: 3

Satisfied: 4

Very satisfied: 5

20. How satisfied are you with your personal relationships?

Very dissatisfied: 1

Dissatisfied: 2

Neither satisfied nor dissatisfied: 3

Satisfied: 4

Very satisfied: 5

21. How satisfied are you with the support you get from your friends?

Very dissatisfied: 1

Dissatisfied: 2

Neither satisfied nor dissatisfied: 3

Satisfied: 4

Very satisfied: 5

22. How satisfied are you with the conditions of your living place?

Very dissatisfied: 1

Dissatisfied: 2

Neither satisfied nor dissatisfied: 3

Satisfied: 4

Very satisfied: 5

23. How satisfied are you with your access to health services?
Very dissatisfied: 1
Dissatisfied: 2
Neither satisfied nor dissatisfied: 3
Satisfied: 4
Very satisfied: 5

24. How satisfied are you with your transport?
Very dissatisfied: 1
Dissatisfied: 2
Neither satisfied nor dissatisfied: 3
Satisfied: 4
Very satisfied: 5

The following question refers to how often you have felt or experienced certain things in the last four weeks.

25. How often do you have negative feelings such as blue mood, despair, anxiety, depression?
Never: 5
Seldom: 4
Quite often: 3
Very often: 2
Always: 1

[Scoring method]
Equations for computing domain raw scores:
Domain 1 (physical) score = Q3 + Q4 + Q10 + Q15 + Q16 + Q17 + Q18
Domain 2 (psychological) score = Q5 + Q6 + Q7 + Q11 + Q19 + Q25
Domain 3 (social) score =Q20 + Q21
Domain 4 (environmental) score = Q8 + Q9 + Q12 + Q13 + Q14 + Q22 + Q23 + Q24

APPENDIX 5

FIVE MAJOR STEPS TO INTERVENTION (THE "5 A'S")

Successful intervention begins with identifying users and appropriate interventions based upon the patient's willingness to quit. The 5 major steps to intervention are the "5 A's": Ask, Advise, Assess, Assist, and Arrange.

1. Ask about tobacco use. Identify and document tobacco use status for every patient at every visit.

2.Advise to quit. In a clear, strong, and personalized manner urge every tobacco user to quit.

3. Assess willingness to make a quit attempt. Is the tobacco user willing to make a quit attempt at this time?

4. Assist in quit attempt. For the patient willing to make a quit attempt, offer medication and provide or refer for counseling or additional treatment to help the patient quit. For patients unwilling to quit at the time, provide interventions designed to increase future quit attempts.

5. Arrange follow up. For the patient willing to make a quit attempt, arrange for follow-up contacts, beginning within the first week after the quit date. For patients unwilling to make a quit attempt at the time, address tobacco dependence and willingness to quit at next clinic visit.

APPENDIX 6

GROUP BEHAVIOURAL TOBACCO CESSATION PROGRAM GUIDE

GROUP TOBACCO CESSATION BEHAVIOURAL PROGRAM

This program is adapted from the Royal University College and World Health Organization…. smoking cessation program1 as used by the Steuben Council on Addictions.

Table of contents

Experiences / challenges

Welcome!

Welcome to the group tobacco cessation behavioural program facilitator's guide. As a facilitator, you play an important role in the quitting process for your group members. Your role is to provide education, foster social support, and encourage members when they face challenges.
The following incorporates the programs strategy to help members quit and stay quit.

Sessions are formatted as a script, but you can improvise and adapt the script as you see fit in order to make the group flow naturally. To encourage group participation and foster discussion, follow the questions in red text throughout the script.

This program includes fortnightly one-hour, in person-based groups for 12 weeks, followed by a monthly meeting for the next 3 months. Start each session by having each group member say hello and provide an update on their quit attempts over the last week. Prompt them to talk about their challenges, successes, and anything else they would like to share. Then introduce that week's session topic. Close each session by encouraging them to practice all they had learnt and heard from others, and to continue making quit attempts.

SESSION 1 (WEEK 1)

1. Introduction to the program and reasons to quit

Introduction to the program

Welcome to our group behavioural cessation program! Congratulations on taking the first step towards quitting smoking and improving your health.

First, as the group facilitator, I want to introduce myself: [Tell the group your name and some background information on yourself. What experience do you have with

smoking cessation? Why do you facilitate this program? Why is smoking cessation an issue close to your heart?]

Now, I'd like everyone to go around and introduce themselves. Tell us:

1. Your name
2. Any concerns you have about quitting
3. At least one reason you are quitting

Next, I'd like to talk about how the group cessation program is formatted:

We shall be having in-person sessions twice a month. We shall meet on times convenient for the group and during your review day.

The focus is on behavioural practical skills, so we shall not be providing tobacco cessation medication. In case someone has severe withdrawal symptoms and will not be able to make quit attempts without medication, we shall advise you on appropriate cessation medication, direct you to pharmacies that sell them; but you will have to drop out of the group session. This is because the focus of the group is to find out how effective behavioural cessation intervention work among people who smoke and also have a diagnosed mental disorder.

This group is intended to be a supportive setting that gives you the opportunity to gain control over your own smoking behaviour. To make sure the environment is supportive for everyone participating, we must agree to follow these three rules:

1. Attend and participate in all the sessions. Your chances of succeeding with the program are much greater if you actively participate. Participating will also help provide a supportive and informative environment for other group members. People look forward to your support. Even if you have difficulty quitting, stick with the program! This is a judgment-free environment that will help you quit and stay quit. When you successfully quit, you will continue to participate in the group until the program comes to a successful end.

2. Do everything the program suggests. While there is no "one way" to quit for everyone, this program incorporates several components that when used together,

will help you on your path to successfully quitting. Keep in mind, sometimes the activities you want to avoid the most are the ones that will help you the most!

3. Give and receive support. Participate in lessons and share your experiences with the group. If you are having an easy time, others in the group may need your support. If you are having difficulties, they are here to support you. Try to participate as much as possible in the group sessions. Social support is proven to help people quit smoking. Use this time to share your questions, frustrations, successes, and more with the group.

[As the group facilitator, you are welcome to add additional rules as you see fit for your group. You can also ask group members if they think there should be any additional rules.]

4. In case you miss three consecutive group sessions you will be dropped from the group. In case you are unable to attend a group session, communicate in advance to the group facilitators.

5. Before discussion for the sessions, we shall be documenting your progress in tobacco cessation (Successful quits and amounts reduced)

We shall have a specific topic to share on each day we meet. We shall also focus on your challenges and successes with quitting, and more information to help you with your tobacco cessation.

Choosing a quit day

Before we continue, you will need to pick a quit date. It should be between two weeks to one month from today. This will give you enough time to get ready but isn’t so far away that you’ll lose interest.

Pick a day that feels comfortable to you. If the day has special meaning to you (e.g., the birthday of someone close to you, an anniversary, and so forth), even better! Try to pick a date that you know won’t be stressful for you for other reasons (e.g., first day of a new job, a time when friends and/or family won’t be available to provide support).

Think about it, and next time we meet, you will share your anticipated quit date with your facilitators.

Reasons for quitting

Share with the group your top 3 reasons to join the group; and particularly your top three reasons to want to quit.

1. ……
2. ……..
3. ……..

Does anyone have any questions or comments before we get started?

Thank participants for sharing. We shall now look at tobacco use disorder.

Can anyone tell me what makes smoking addictive? [Allow participants to discuss. If other comments come up, give them positive reinforcement for their participation. When someone says, “Nicotine,” move on to discuss.]

Nicotine is the addictive substance in tobacco. It’s what keeps you coming back for more. Each time you puff on a cigarette the nicotine level in your blood increases rapidly and you get a pleasurable feeling. You really like that feeling. When you finish the cigarette and your nicotine level drops below a certain amount, you feel withdrawal (anxiety, irritability, and impatience). You really don’t like that feeling! You smoke, then, to maintain the good feeling and to prevent withdrawal.

It is important to note that tobacco smoke has 7000 chemicals, out of which 70 are known to cause cancer.

Tobacco smoking can damage every part of the body, causing many actual medical conditions such as shortness of breath, exacerbation of asthma and respiratory infections as well as many chronic diseases including heart disease, strokes, cancer, chronic respiratory diseases and TB.
Tobacco use has also been shown to exacerbate mental illness

The more you smoke, the higher dosage of psychotropics you will need- which could prove more expensive.

What are some of your triggers? Let's go around and everyone can name one or two of their triggers.

Summarise participants reasons for wanting to quit, and encourage them for the decision made to quit.

That concludes our session for this week.

Next week we will talk in depth about benefits of quitting and understanding why we smoke and ways of quitting

SESSION 2 (WEEK 3)

2. Benefits of quitting and understanding why we smoke and ways of quitting; setting quit date

Review of experience since last sessions. Any positive experiences or challenges experienced? Go round the group and allow each member to share their experience.

Today we shall start by discussing on benefits of quitting tobacco use.

What are some benefits that you will have once you successfully quit?

Go round and allow everyone to share their anticipated benefits

BENEFITS OF QUITTING

From 20 minutes to 20 years, the benefits of quitting smoking last a lifetime.

20 minutes after quitting -Your blood pressure drops and the circulation in your hands and feet improves.

12 hours after quitting -The carbon monoxide level in your blood returns to normal.

2 days after quitting-Your taste and smell senses improve.

2 weeks to 3 months after quitting-Your heart attack risk drops and your lung function improve.

1 to 9 months after quitting- Your coughing and shortness of breath decrease.

1 year after quitting - Your added risk of heart disease is half that of a smoker's.

5 to 15 years after quitting - Your risk of stroke is now equal to a non-smoker's.

10 years after quitting- If you are an average smoker (one pack a day) your lung cancer death rate drops by almost half. Risk of cancers of the mouth, throat, esophagus, bladder, kidney, and pancreas decreases.

15 years after quitting - Your added risk of heart disease is the same as a non-smoker's.

For more emphasis on benefits of quitting, let's look at cost of tobacco use.

How much money you can save if you quit?

- Total money spent on tobacco per day
- The amount of money spent per year
- The amount of money spent in ten years
- You can buy many things with the money saved:

Understanding why we smoke

People use tobacco for many reasons

- Addiction
- Social activity
- Stress relief
- Emotional support
- Boredom/filling in time
- Everyone does it
- Sharing of cigarettes
- Bonding/acceptance

STRATEGIES AND SKILLS FOR QUITTING

After you quit, expect to make changes in the way you think and act. Below are a number of ways to cope with triggers. Identify the ones that work for you. What works for you might not work for someone else.

1. Make sure all cigarettes are destroyed. Do not keep any in your house, pockets, or at work.
2. Get rid of all smoking reminders such as ashtrays, lighters and match sticks
3. Clean your clothes to rid them of the cigarette smell, which can linger for a long time.
4. Ask your friends or family who smoke to not smoke around you and not offer you cigarettes.
5. Remind your family and friends that you are quitting. Ask them to help you over the rough spots of the first couple of days and weeks.
6. Call someone and talk about your feelings.
7. Change your routine
8. Drink lots of water (eight glasses per day).
9. Keep busy.
10. Stay in non-smoking areas as much as possible.
11. Get plenty of rest.
12. Distract yourself, do something different from what you were doing for 5-minute when you feel a craving for tobacco.
13. Take a walk or engage in other exercise.
14. Try deep breathing and/or relaxation exercises. (We shall practice during the session)
15. Brush your teeth more often than usual.
16. Keep your hands busy (e.g., handle a coin or polished rock, stick).
17. Leave a situation when the urge to smoke is strong.
18. Wear a rubber band around your wrist and snap it when you have strong urges to smoke.
19. Distract yourself by engaging in a hobby or pleasurable activity.
20. Review the list of reasons why you want to quit.
21. Remind yourself of the health benefits of quitting.

22. Remind yourself of the money you'll save by not smoking.
23. Think about how hard you've worked to manage your mental health condition and how much quitting will help.
24. Remind yourself that the urge to smoke will go away in a few minutes.
25. Recognize that "just one" cigarette can undo all your hard work and lead to a relapse.
26. Think about some aspect of smoking that is negative to you.
27. Take it a minute/day at a time. Think of quitting in terms of one day at a time or one urge at a time.
28. Think of being a good role model for someone you love and how quitting will enable you to do more things with this person.
29. Limit or avoid coffee and caffeinated drinks. Reduce caffeine intake by 50% when you quit to avoid some common withdrawal symptoms such as insomnia.
30. Avoid alcoholic beverages.

That concludes our session for this week.

Before we disperse, last session you had an assignment of choosing a quit date. Kindly share with us your identified quit date. (Facilitator note them down for each individual).

Next week we will talk in depth about Withdrawal symptoms and social support

SESSION 3 (WEEK 5)

3. Withdrawal symptoms and social support

Review of experience since last session. Any positive experiences or challenges experienced? Go round the group and allow each member to share their experience.

Today we shall start by discussing withdrawal symptoms and social support.

What are some benefits that you will have once you successfully quit?

Go round and allow everyone to share their experiences with withdrawal.

Ask: What are some of the negative effects you get when you have tried quitting in the past?

Common withdrawal symptoms

- Headaches
- Coughing
- Cravings
- Increased appetite or weight gain
- Mood changes (sadness, irritability, frustration, or anger)
- Restlessness
- Decreased heart rate
- Difficulty concentrating
- Flu-like symptoms
- Insomnia

COPING WITH NICOTINE WITHDRAWAL

Nicotine withdrawal symptoms usually last from 2-4 weeks. Below are a list of common withdrawal symptoms and some suggestions for coping with them.

Withdrawal Symptoms	**Coping Strategy**
Craving	Distract yourself
	Do deep breathing exercises (as shown in group)
	Realize the urge will pass
Irritability	Use progressive muscle relaxation exercises (Discuss in session)
	Exercise (anything that works for you)
	Listen to soothing music

Insomnia	Take a walk several hours before going to bed
	Unwind by reading for a while
	Take a warm bath
	Eat a banana or drink warm milk
	Avoid beverages with caffeine after noon and reduce caffeine by 50% upon quitting
Withdrawal Symptoms	**Coping Strategy**
Increased appetite	Pace your meals
	Drink water or low-calorie liquids
Fatigue	Get more exercise
	Get an adequate amount of sleep each night
	Take a nap
	Try not to push yourself too hard for the first 2-4 weeks after quitting
Constipation, gas, or stomach pain	Drink plenty of fluids
	Add roughage to your diet (e.g., fruit, raw vegetables)
Dry mouth; sore throat, gums, or tongue	Sip ice-cold water or fruit juice
	Chew gum (PK-blue with menthol)
Headaches	Take a warm bath or shower
	Try relaxation or meditation exercises

Drink plenty of water

GETTING SUPPORT

Choosing to quit is a tough decision. You must do it for yourself, but you don't have to do it alone. Asking for help is a key part of the quitting process. Think about who can help you quit. Consider family members and other people with whom you spend a lot of time. Also consider getting support from former smokers and group members who have successfully quit.

To help yourself quit, you can:

Tell everyone that you're quitting and when

Ask family, friends, and roommates to smoke outside

Ask a friend or spouse to quit with you

Make a list of people who can give you support

That concludes our session for this week.

Next week we will talk in depth about dealing with stress, anxiety and coping with depression.

SESSION 4 (WEEK 7)

4. Dealing with stress and anxiety and coping with depression

Review of experience since last session. Any positive experiences or challenges experienced? Go round the group and allow each member to share their experience.

Today we shall start by discussing dealing with stress and anxiety and coping with depression.

What are some of your experiences with stress and anxiety? How did you cope?

Have you ever experienced depression? How have you coped before?

Go round and allow everyone to share their experiences.

STRESS/ANXIETY MANAGEMENT

This week we're going to focus on stress and anxiety to begin with. Stressful situations can tempt almost any recent quitter to reach for a cigarette. That's why it is important for new nonsmokers to review their lives and eliminate as much stress as possible. Then, they must also plan ahead and learn new ways to deal with the stress that does happen.
We will first look at the myth that smoking somehow magically gets rid of all the stress in one's life. Next, we will examine powerful, proven strategies to deal with stress in healthy, productive ways. You will then be asked to devise your own personalized stress management plan. This plan will provide you with the means to deal with the stress in your life without being tempted back to smoking.

Introduction

Stress is an internal response to outside events. In a very real way you create your own stress by choosing how you will react to a given situation.

Smoking and Stress Management

How many of you find yourselves smoking more when you're stressed?
Many smokers believe that smoking somehow gets rid of all the stress in their life or helps them deal more effectively with the problems that do occur. You may be surprised to learn that smoking actually increases stress on the body.

Understand that there is no chemical in a cigarette that calms you. In fact the opposite is true. The chemicals in cigarettes stimulate your heart to beat faster and increase your blood pressure.
However, many smokers do report that they feel more calm and relaxed when they smoke. Why is that? Three things are happening:
1) First, when you smoke you practice deep breathing. This is the same kind of breathing that we have been practicing. That way of breathing actually does relax you. That's why it's used many different situations.

2) Secondly, when you smoke while tense, you are shifting focus from whatever it is that is bothering you. Whether you actually take a break or simply stop to smoke for a minute or two, you are no longer focusing on the issue at hand. Your mind is on the act of smoking. This shift of focus reduces anxiety and tension.
3) Finally, as you know by now, back when you smoked your body was used to a certain amount of nicotine. When your blood nicotine level dropped below that amount you began to feel irritable, anxious, and impatient – all the same feelings that most people experience when under stress. So you smoked a cigarette to relieve the withdrawal and you felt better. Putting more nicotine into your body simply relieved the withdrawal, but since you felt better you mistakenly equated that with reducing stress. Doing this unconsciously during many stressful times over the years reinforced that notion. It is important to clearly understand now that relieving withdrawal is not the same as relaxing or becoming calm.

You might realize that you found yourself when you faced a difficult situation. And felt better in the process. You began to believe that the cigarette somehow helped you and that you couldn't cope without it.
But think back to some stressful time. Can anyone share an example? Did the situation resolve itself simply because you had a cigarette? Of course not. You resolved the issue, not the smoking.
Now is the time to take back the power you have given cigarettes. Give yourself credit for something that you have been doing on your own all along.

Let's talk about some helpful suggestions to help you construct a new stress management strategy:

1. Take long, slow, deep breaths as often as you can throughout the day but especially during times of stress.
2. When you encounter a problem, step back, take a few minutes to think things over, then proceed.
3. Separate the cigarette from the situation. Think back to situations that you find of stressful. Ask yourself what a cigarette could do to make those situations better.

4. If you become angry with someone, tell yourself, “If I smoke I will only hurt myself, not that person.” Smoking is simply not a good way to get back at anyone.
5. Close your eyes and practice seeing yourself handling a stressful situation without a cigarette. See someone offering you a cigarette but you turning it down. Practice saying, “I can deal with this without smoking.”
6. Stop tolerating. Every day we put up with all kinds of situations that sap our energy and cause unnecessary irritation.
7. Slow down. Part of the stress in our lives can be traced to our increasingly fast -paced life style. We just rush from one thing to another without a minute to ourselves. No wonder we are so frazzled. Here are a few tips to help you reduce the pace of your life and “stop and smell the roses.”
8. Create a place at home and at work where you can be quiet and peaceful. “Hide” there ever so often.
9. Don’t live by such a rigid schedule that you have to be someplace every moment of every day. Do something spontaneous every day.
10. Eat slowly. Set aside plenty of time for meals. Don’t eat in your car, at your desk, or on the run.
11. Turn off the pager, cell phone, TV and radio. Just being quiet for a few minutes every day.
12. Stop yourself when you are rushing around like crazy. Ask yourself, “Why am I doing this?” The answer may give you some important insight.
13. Meditate or pray. Set aside at least half an hour every day to do so.
14. Allow some time each week to play. This does not mean that you need to participate in some type of organized sport (although that’s great if you want to do so). Rather, give yourself ample time to just have fun, whatever that means for you.
15. Set aside fifteen or twenty minutes every day to practice the Relaxation Technique found in this booklet. This powerful technique has been used successfully by thousands of individuals for many years.

Now that you have some excellent stress management suggestions, take a few minutes to devise your Personalized Stress Management Plan.

- What are some of the suggestions you find to be the most helpful for you?

- Does anyone have any other suggestions that aren't on the list?

COPING WITH DEPRESSION

Depression is a common mental health problem that involves a low mood and a loss of interest in activities, causing a significant impairment in daily life.

Common presentations of depression:

- Multiple persistent physical symptoms with no clear cause
- Low energy
- Fatigue
- Sleep problems (too much/too little)
- Anxiety
- Significant change in appetite or weight (Gain or loss)
- Beliefs of worthlessness
- Excessive guilt
- Indecisiveness
- Restlessness/Agitation
- Hopelessness
- Suicidal thoughts and acts

That concludes our session for this week.
Next session we will talk in depth about assertiveness and anger management

SESSION 5 (WEEK 9)

5. Assertiveness training and anger management

Review of experience since last session. Any positive experiences or challenges experienced? Go round the group and allow each member to share their experience.

Today we shall start by discussing assertiveness and anger management.

How have you been managing your anger?

Are you able to stand up for yourself without becoming aggressive?

Go round and allow all the members to share their experiences.

Assertiveness is the ability to express one's feelings and assert one's rights while respecting the feelings and rights of others.

Assertiveness skill

- Tension control
- Inner calm
- Positive thinking
- Self-awareness
- Positive language and self-talk
- Positive affirmations (an attempt to re-program your sub-conscious mind)

Ways to be assertive

- Be decisive
- Take responsibility for your actions
- Say NO when you need to
- Be an attentive listener
- Communicate clearly
- Say YES when you need to
- Ask for what you want
- Follow your intuition
- Feel free to take a chance
- Stand up for yourself

ANGER MANAGEMENT

Anger is a basic human emotion that is experienced by all people; typically triggered by an emotional hurt.

Anger management Skills

- Take a deep breath and count until 50 slowly
- Drink water- a lot of it
- Think of the person who makes you smile
- Listen to music
- Positive self-talk; or vent it all out in a safe place
- Distract yourself- play games, do something different from the one you were doing
- Step out- Get some fresh air. Take a walk

Practice deep breathing and meditation.

- You can do this several times until you feel relaxed:
- Find a quiet place
- Sit down.
- Close your eyes.
- Control your breathing.
- Place a hand over your stomach.
- Slowly inhale to feel your stomach rise.
- Exhale to feel your stomach contract.

Practice visualization.

- Visualization can instantly relieve tension and anxiety. Take a few moments to sit in a chair or lie down in a quiet room and close your eyes. Imagine yourself in pleasant, calm surroundings. Imagine the sounds of water, the warmth of the sun, and the smell of sand, grass, or fresh air, or another calming scenario.

That concludes our session for this week.

Next week we will talk in depth about tobacco free lifestyle, relapse prevention (dealing with high risk situations)

SESSION 6 (WEEK 11)

3. Tobacco-free lifestyle and dealing with high risk situations

Welcome to our last week of the intensive cessation program! You've now been quit for eleven weeks! For those who haven't succeeded in completely quitting, you have made a lot of progress in reducing the amount you used to smoke. Congratulate yourself!

Review of experience since last session. Any positive experiences or challenges experienced? Go round the group and allow each member to share their experience.

Today we shall start by discussing tobacco free lifestyle and relapse prevention (dealing with high risk situations)

RELAPSE PREVENTION

1. How do you all feel about it?
2. How has this journey been for you?

Let's go around and everyone can share their experiences thus far. Share your struggles, your accomplishments, and your goals.

Now it is time to turn our attention to staying quit. The best way to do that is to know which situations are likely to be problematic and have a plan ready to deal with them. Without proper planning, the likelihood of relapse increases dramatically.

Preventing a Smoking Relapse

To prevent a relapse, keep your guard up for at least one year after quitting. A number of triggers can tempt you to return to smoking including:

- A flare-up of negative moods, like depression or anger
- A crisis or some event that makes you feel stressed out
- Drinking alcohol/ using other substances (cannabis, khat)
- Positive moods and relaxation that makes you want to “reward” yourself with a smoke
- Being around other people who are smoking

RECOVERING FROM A LAPSE TO SMOKING: DO’S AND DON’TS

It is not uncommon for successful ex-smokers to have had a smoking lapse along the way. A smoking lapse usually consists of smoking a few cigarettes or smoking for a day or two. Avoiding a smoking lapse should be your first goal. However, if a lapse occurs, it is vital to prevent the lapse from becoming a full-blown relapse to regular, daily smoking.

Even if you return to any smoking at all, you can still achieve success and become a permanent non-smoker. Remember, most permanent ex-smokers tried to quit multiple times before they achieved their goal.

DO

Put out your cigarette. Get rid of all other cigarettes in your home, pocket, and place of work.

View your smoking lapse as a slip or mistake, not a personal failing. All is not lost because you lapsed. Your return to smoking is not a matter of lacking willpower—it’s a matter of lacking preparation for coping with smoking triggers and situations. That’s a problem that can be fixed!

Learn from smoking lapses by identifying the smoking trigger and analyzing the problem that led to your return to smoking.

DON’T

Beat yourself up by feeling guilty or like a failure for smoking. These feelings will just make you want to smoke more.

Put off quitting smoking again until later, when the stress or other reason for your lapse goes away. Stress is part of life; it will always be there in one form or another. Trying to quit as soon as possible after a failed attempt is easier than waiting until you're fully addicted to nicotine again.

Identify your smoking triggers. Some examples could include:

- Nicotine cravings
- Needing to handle something (ritual of lighting up)
- Needing an energy boost (When tired)
- Feeling down, depressed, or bored
- Feeling stressed out
- Relaxation (when relaxing)
- Feeling angry
- Feeling "up" and positive
- Social situations (parties, hanging around smokers)
- When my friends or family invite me to smoke with them
- Drinking alcohol or being around others who are drinking
- Other activities of daily living (after a meal, talking on the phone, waking up in the morning)

Staying Quit

Prevent the possibility of relapse by following this simple advice:

1. Where else might you be tempted to smoke that was not so obvious to you a few weeks ago?
2. What stress management strategies have you been using?
3. Discuss your triggers and how you plan to handle the situation.

TOBACCO FREE LIFESTYLE

You might be feeling like you've lost some of the pleasure in life. But that doesn't have to be the case. When you stop smoking, your senses of taste and smell start to come back to life. So does your feeling of being in direct contact with the world, without a smoke screen to hide behind. You can enjoy a long trip without a craving.

You are free to go anywhere without worries of a smoking point or running away from the city council askari!

Here are some ideas to get you started (or come up with your own):

- Watch movies/football.
- Build or make something.
- Play football
- Take an afternoon nap.
- Have a party.
- See old friends who don't smoke
- Play with kids
- Join a group e.g. church group
- Do volunteer work.

That concludes our session for this week.

At the end of the session, participants to complete the WHOQOL form. All participants who report successful quit, and consent to cotinine testing, to be tested.

Next session will be our first follow up monthly session. We shall share our experiences- strengths and challenges since our session today.

FOLLOW UP SESSIONS

After touching base with the participants, record the number of cigarettes smoked. Then have a round of discussions.

Session 7 (Week 16)

Round of discussion on participants' feelings, cessation attempts, barriers experienced and how they coped.

Session 8 (Week 20)

Round of discussion on participants' feelings, cessation attempts, barriers experienced and how they coped.

Session 9 (Week 24)

Round of discussion on participants' feelings, cessation attempts, barriers experienced and how they coped.

At the end of the session, participants to complete the WHOQOL form. All participants who report successful quit, and consent to cotinine testing, to be tested

Thank all the participants for their participation.

APPENDIX 7

FOCUS GROUP DISCUSSION GUIDE

Group Tobacco Cessation Behavioural Intervention Study

Ground rules

1. The most important rule is that only one person speaks at a time. There may be a temptation to jump in when someone is talking but please wait until they have finished.
2. There are no right or wrong answers
3. You do not have to speak in any particular order
4. When you do have something to say, please do so. There are many of you in the group and it is important that I obtain the views of each of you
5. You do not have to agree with the views of other people in the group

Warm up

- First, I'd like everyone to introduce themselves. Can you tell us your name?

Guiding questions

Week 1:

1. What made you decide to be part of this group tobacco cessation program?
2. What do you expect to receive from this program?

Of all the things we've discussed today, what would you say are the most important issues you would like to express about today's session?

Week 2:

1. What are some of the effects about tobacco use that you know/ or have heard of?
2. What are some of the benefits of quitting tobacco use, according to you?

Of all the things we've discussed today, what would you say are the most important issues you would like to express about today's session?

Week 3:

1. What type of withdrawals have you experienced?
2. How have you coped with the withdrawal symptoms experienced?

Of all the things we've discussed today, what would you say are the most important issues you would like to express about today's session?

Week 4:

1. What are some of the ways you cope with stress?
2. What things/events cause you stress?

Of all the things we've discussed today, what would you say are the most important issues you would like to express about today's session?

Week 5:

1. How would you deal with a friend who was offering you a cigarette?
2. What are some of the situations that increase your tobacco use?

Of all the things we've discussed today, what would you say are the most important issues you would like to express about today's session?

Week 6:

1. What are some of the barriers you have experienced in your cessation attempt?
2. What facilitators do you find work for you, in your cessation attempt?
3. What are some other facilitators that you have used that work for you and are not part of the program?

Of all the things we've discussed today, what would you say are the most important issues you would like to express about today's session?

Week 7, 8, 9:

1. How has your experience been since you started the program?
2. What are the barriers you are experiencing?
3. How are you coping with those barriers?

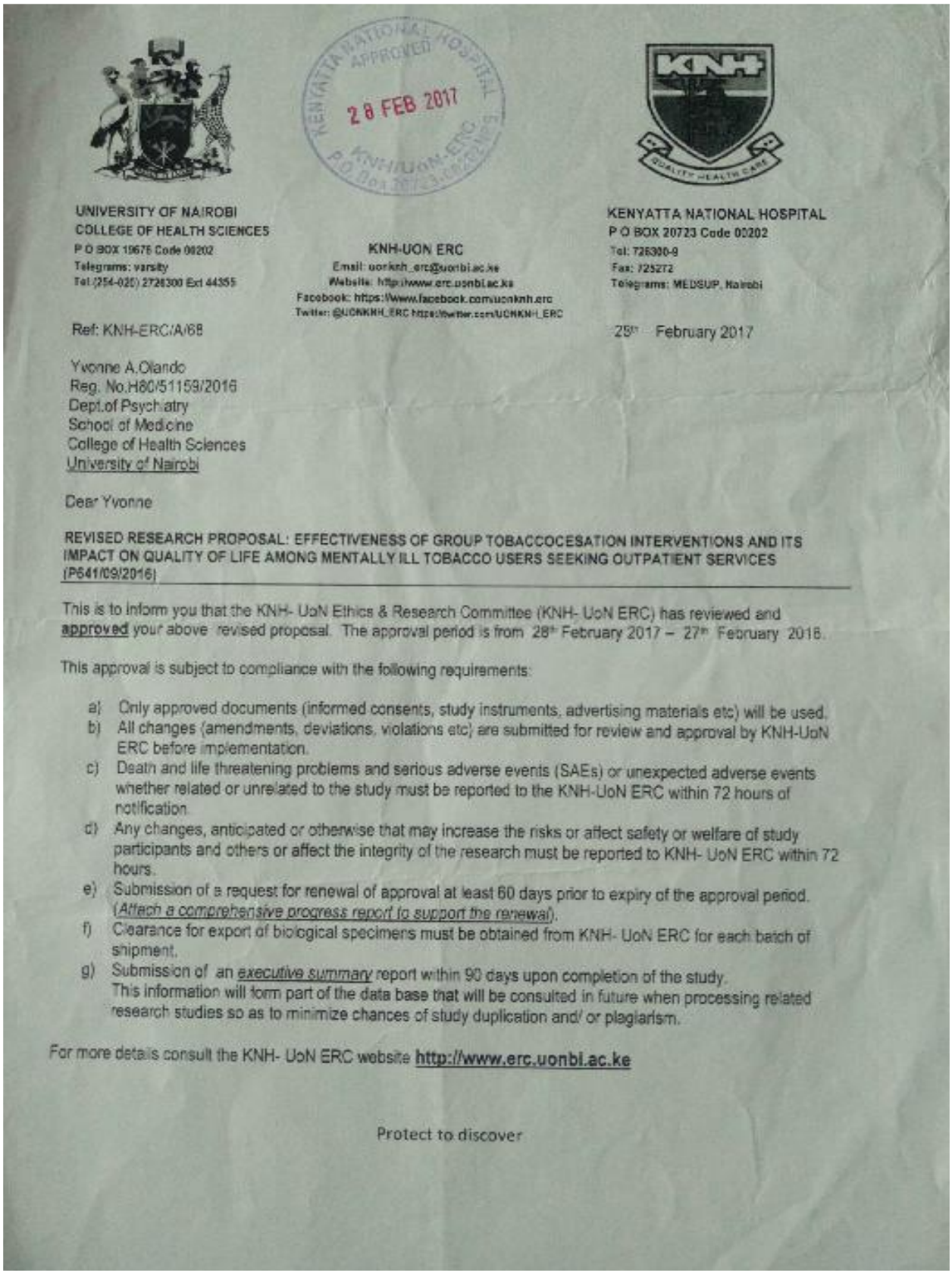
Of all the things we've discussed today, what would you say are the most important issues you would like to express about today's session?

Conclusion:

- Thank you for participating. This has been a very successful discussion
- Your opinions will be a valuable asset to the study
- We hope you have found the discussion interesting
- I would like to remind you that any comments made in this group will be anonymous

APPENDIX 7

ETHICAL APPROVALS



KENYATTA NATIONAL HOSPITAL APPROVED 28 FEB 2017 KNH/UON-ERC P.O. Box 20723-00202 NAIROBI

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Ref: KNH-ERC/A/68

25th February 2017

Yvonne A.Olando
Reg. No.H80/51159/2016
Dept.of Psychiatry
School of Medicine
College of Health Sciences
University of Nairobi

Dear Yvonne

REVISED RESEARCH PROPOSAL: EFFECTIVENESS OF GROUP TOBACCOCESATION INTERVENTIONS AND ITS IMPACT ON QUALITY OF LIFE AMONG MENTALLY ILL TOBACCO USERS SEEKING OUTPATIENT SERVICES (P641/09/2016)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above revised proposal. The approval period is from 28th February 2017 – 27th February 2016.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

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Yours sincerely,

PROF M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Assistant Director, Health Information, KNH
The Chair, KNH-UoN ERC
The Dean, School of Medicine UoN
The Chair, Dept. of Psychiatry, UoN
Supervisors: Prof. Mary Wangari Kuria, Dr. Muthoni Mathai, Dr. Mark Huffman

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Ref. No.KNH/ERC/R/87

April 18 2018

Yvonne A. Olando
Reg. No.H80/51159/2016
Dept. of Psychiatry
School of Medicine
College of Heath Sciences
University of Nairobi

Dear Yvonne

Re: Approval of Annual Renewal – Effectiveness of group tobacco cessation interventions and its impact on the quality of life among mentally ill tobacco users seeking outpatient services (P641/09/2016)

Refer to your communication dated April 6, 2018.

This is to acknowledge receipt of the study progress report and hereby grant annual extension of approval for ethical research protocol P641/09/2016.

The approval dates are 28th February 2018 – 27th February 2019.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH- UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH- UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).

f) Clearance for export of biological specimens must be obtained from KNH- UoN-Ethics & Research Committee for each batch of shipment.

g) Submission of an executive summary report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M.L. CHINDIA
SECRETARY, KNH-UON ERC

c.c. The Principal, College of Health Sciences, UoN
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Ref. No.KNH/ERC/R/55

March 29, 2019

Yvonne A. Olando
Reg. No.H80/51159/2016
Dept.of Psychiatry
School of Medicine
College of Health Sciences
University of Nairobi

Dear Yvonne

Re: Approval of Annual Renewal – Effectiveness of group tobacco cessation interventions and its impact on the quality of life among mentally ill tobacco users seeking outpatient services (P641/09/2016)

Refer to your communication dated March 22, 2019.

Upon review of your communication, the KNH-UON ERC hereby grants you annual extension approval for ethics research protocol **P641/09/2016.**

The approval dates are 28th February 2019 – 27th February 2020.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN- ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
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g) Submission of an *executive summary* report within 90 days upon completion of the study
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M.L. CHINDIA
SECRETARY, KNH-UON ERC

c.c. The Principal, College of Health Sciences, UoN
The Director CS, KNH
The Chairperson, KNH-UoN ERC
The Dean, School of Medicine,UON
The Chair, Dept. of Psychiatry,UON
Supervisors: Prof.Mary Wangari Kuria, Dr. Muthoni Mathai, Dr.Mark Huffman

MATHARI HOSPITAL

CLEARANCE TO UNDERTAKE RESEARCH IN MATHARI HOSPITAL

TO: HEALTH RECORDS I/C Dates 11/07/2017

This is to inform you that (name/no. of students)

VHONNE O LANDO

From (Name of training institution)

UNIVERSITY OF NAIROBI

Has/~~have~~ been cleared by the office of the Medical Superintendent to undertake research at Mathari hospital from 11/7/2017 to JANUARY 2018

Please accord them/him/her the necessary support.

Thanks

In-Charge C.M.E.D

CONDITIONS

1. The License is valid for the proposed research, research site specified period.
2. Both the Licence and any rights thereunder are non-transferable.
3. Upon request of the Commission, the Licensee shall submit a progress report.
4. The Licensee shall report to the County Director of Education and County Governor in the area of research before commencement of the research.
5. Excavation, filming and collection of specimens are subject to further permissions from relevant Government agencies.
6. This Licence does not give authority to transfer research materials.
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