Effect of a group tobacco cessation behavioral intervention among patients with mental illness in Kenya: Results from a controlled clinical trial

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ABSTRACT

INTRODUCTION Individuals with mental disorders are more susceptible to initiating and sustaining tobacco use; unfortunately, most do not get support to quit. Group behavioral counselling, an effective low-cost strategy for cessation has been shown to be effective, yet has not been studied among this population in Kenya.

METHODS Mentally ill tobacco users at Mathari Referral and Teaching Hospital's Clinic for Substance Abuse Treatment in Nairobi, were recruited from September 2017 to March 2019. Participants were allocated into intervention and control groups (1:1). Intervention group participants met in groups of 10 over a 24-week period to participate in group behavioral counselling sessions using a structured curriculum to promote cessation. Control group participants received usual care. The primary outcome was tobacco cessation at 24 weeks measured through salivary cotinine strips. Secondary outcomes included self-reported number of cigarettes/sticks used daily and health-related quality of life (HRQOL), using the WHOQOL Brief Questionnaire at 24 weeks. Between-group event rates were compared using Cox proportional hazards models, while differences in HRQOL scores were analyzed using paired t-tests.

RESULTS Participants' mean age was 35 (SD=9) years, 87% were male, and 42% had completed secondary education. Over half (65%) had substance use disorders (diagnosed) and 15% had major depressive disorders. Most participants (94%) used cigarettes at baseline and participants smoked for a mean of 13 (SD=11) years with an average of 14 (SD=7) sticks daily. Intervention group participants reported a higher cessation rate (15.2% vs 0%, p=0.02 at week 12, and 9.1% vs 0%, p=0.10 at week 24), with a lower number of sticks smoked (97% vs 58.6%, p<0.0001) compared with control group participants at 24 weeks follow-up. Intervention group participants reported higher change in HRQOL scores compared to control participants in physical (30.6% vs 10.4%: OR=3.79; 95% CI: 1.25–11.48) and environmental domains (34.7% vs 8.3%: OR=5.84; 95% CI: 1.79–19.03) at end of study.

CONCLUSIONS The group behavioral intervention among tobacco using Kenyans with mental illness led to improved tobacco cessation outcomes.

INTRODUCTION

The prevalence rate of major mental disorders among adults in Kenya is at 4%[1]. Tobacco use is also common in Kenya; 2.5 million adults (11.6% of adults, 19.1% of men, and 4.5% of women) reported using tobacco in the 2014 Global Adults Tobacco Survey-Kenya (GATS)[2], which was the highest prevalence in Sub-Saharan Africa[3]. Individuals with serious mental disorders are more likely to use tobacco[4], present with more intensive psychiatric symptoms, poorer health outcomes, and greater functional deterioration when compared to non-tobacco users[5]. They smoke at twice to quadruple the rate of the general population[6]. Studies have shown that people with mental illness want and/try to quit at the same rate as the general population, but experience less

success, even though quitting may improve mental health outcomes[7]. A study exploring the motivation to quit smoking in a South African male psychiatric unit, confirms that, similar to populations elsewhere, rates of cigarette smoking among psychiatric inpatients in South Africa is high. While patients are motivated to quit smoking, few were provided with necessary advice and support[8].

The harmful effects of tobacco use have been widely recorded, with tobacco-related illnesses including cancer, heart disease, and lung disease, being among the most common mortality causes of all persons and those with mental illness[9]. Tobacco cessation reduces the risk of early death and improves health-related quality of life[10]. The Kenya National Tobacco Control Action Plan[11] and National Tobacco Treatment and Dependence Clinical Guidelines[12] recognize the availability of smoking cessation support as a key intervention, with provision of brief advice by healthcare providers to recommend tobacco cessation identified as an effective intervention to motivate and support patients' quit attempts. A Narrative Review of Intensive Group Tobacco Treatment (n = 11 observational studies), including weekly group sessions led by a professionally trained clinician, found that group treatments had a higher 4-week carbon monoxide validated quit rate (range: 35.5%–67.3%) than individual treatments (range: 18.6%–53.3%)[13].

Despite the well-known hazards of tobacco use and benefits of cessation, implementation of evidence-based interventions for tobacco cessation is limited among patients with mental illness in Kenya. Further, patients and healthcare providers have limited knowledge and practice on how to treat tobacco dependence in this context[14]. The relatively high costs of tobacco cessation pharmacotherapies[15] and limited number of trained healthcare workers to treat tobacco dependence in Kenya as a whole, suggest that alternative strategies are needed to promote cessation[16].

Therefore, this study primarily sought to evaluate the effect of a group tobacco cessation behavioral intervention on cessation, and secondly on smoking reduction and health-related quality of life among tobacco using patients with concomitant mental illnesses at 24 weeks.

METHODS

Study design

We used a controlled clinical trial design 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. However, tobacco cessation counselling is not routinely provided (patients are not routinely offered brief tobacco cessation intervention or offered NRTs or cessation medication). The Kenyatta National Hospital/University of Nairobi Ethics review committee (KNH/UON ERC) and the National Commission for Science Technology and Innovation ethics committees approved the protocol, which was registered at clinicaltrials.gov (NCT04013724). All participants provided written informed consent after receiving a complete description of the study.

Participants/sample

Adults (aged ≥18 years) with a history of tobacco use for more than six months, high nicotine dependence measured by a Fagerström[17] score of ≥6, ongoing outpatient follow-up for a diagnosed mental health condition (such as substance use disorder, depression, anxiety, schizophrenia and bipolar), and willingness to participate in the study for six months were eligible. Patients who were on nicotine replacement therapy (NRT) or other pharmacotherapy for tobacco cessation, and those currently experiencing severe psychotic episodes as determined by their treating mental healthcare provider, and those who would not consistently participate in the group sessions for whatever reason, were excluded from the study. Study staff recruited participants through presentation at CSAT and outpatient follow-up clinics.

Randomization and blinding

From September 2017 to March 2019, participants were recruited in groups of 10 for assignment into the intervention and control groups. The first 10 participants formed group 1, the intervention group, and the next 10 participants formed group 2, the control group. This procedure continued until all 10 groups were formed (5 intervention and 5 control groups). The intervention staff were aware of the group assignment, but the staff conducting the biochemical verification were blinded to participants' allocation.

Intervention group

Prior to recruitment, the principal investigator (PI) trained two counsellors who assisted with recruitment, screening, intake, and registration. Two addiction therapists who were not hospital staff were recruited and trained by the PI to lead group tobacco cessation sessions tailored to patients with mental illness. The group behavioral tobacco cessation intervention consisted of six sessions over 12 weeks, followed by monthly group follow-up meetings from weeks 14 to 24, which were led by the PI. The study did not include NRTs as they are expensive in Kenya and not affordable to most of the population under study. The study sought an intervention that would be easy to sustain and replicate. The program and curriculum were 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[18,19]. The timeline and session topics covered during the program are shown in Supplementary file Table 1.

Follow-up sessions

During the study period, participants continued attending the CSAT and outpatient follow-up programs. Facilitators

conducted monthly behavioral group sessions 7–9 during weeks 14–24, which included facilitating discussions on participants' feelings, cessation attempts, barriers experienced and coping skills; and participants were offered support as per their individual experiences/challenges. Challenges raised were documented and practical and

Table 1. Baseline sociodemographic characteristics of study participants

Characteristics	Intervention (n=49)	Control (n=48)	p
	Mean (SD)	Mean (SD)	
Age (years)	33.4 (6.0)	36.1 (11.4)	0.15
Number smoked/chewed per day	12.9 (7.0)	13.9 (6.5)	0.43
Years using tobacco	11.6 (6.4)	12.7 (10.8)	0.57
Age of first tobacco use	19.5 (5.3)	22.1 (8.8)	0.08
Fagerström score	5.9 (1.5)	5.7 (1.7)	0.52
	n (%)	n (%)	p
Male	38 (78)	45 (94)	0.02
Primary tobacco product			0.30
Cigarette	48 (98)	45 (94)	
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)	
Education level			
None	1 (2.0)	0 (0)	0.42
Primary	15 (30.6)	14 (29.2)	
Secondary	22 (44.9)	19 (39.6)	
College (1–2 years post high school)	10 (20.4)	10 (20.8)	
University (>4 years post high school)	1 (2.0)	5 (10.4)	
Occupation			
Unemployed	22 (44.9)	15 (31.3)	0.10
Student	3 (6.1)	0 (0)	
Self employed	12 (24.5)	21 (43.8)	
Employed	12 (24.5)	11 (22.9)	
Retired	0 (0)	1 (2.1)	
Self-assessed general health			
Poor	7 (14.3)	9 (18.8)	0.79
Fair	20 (40.8)	17 (35.4)	
Good	22 (44.9)	22 (45.8)	
Use of alcohol and other drugs			
Yes	33 (67.3)	37 (77.1)	0.45
No	14 (28.6)	11 (22.9)	
No response	2 (4.1)	-	

*No response: no feedback received from participants.

supportive therapy related to reported challenges was offered.

Control group procedures

During the study period, the control group participants continued receiving usual care (follow-up for their psychiatric condition), including clinical care at CSAT. The participants responded to questionnaires for outcome assessment at the end of weeks 12 and 24. The control group was offered the intervention sessions that were offered to the intervention group at the end of the study.

Outcome measures

Participants who reported tobacco use abstinence at weeks 12 and 24 of follow-up and consented to a saliva test, were tested using a nicotine cotinine strip (Devon Medical, Pennsylvania, USA). The primary outcome was biochemically verified tobacco cessation at week 24. Nurses working at the hospital who were blinded to treatment allocation, and were not part of the study, assessed the saliva test results. Previous tobacco cessation intervention trials, treated lack of reports of abstinence as positive cotinine results; as such the study treated those who did not report abstinence the same way[20]. Secondary outcomes assessed included: rates of tobacco cessation at week 12, number of quit attempts, reduction in number of cigarettes/sticks used per day at 24 weeks, and HRQOL at 24 weeks. We performed additional *post hoc* analyses evaluating the proportion of individuals who reduced their smoking, less than two cigarettes or kuber (smokeless tobacco), per day.

Data collection

Sociodemographic characteristics of the study participants, such as age, sex, residence, education level, occupation, and perceived health status, were reported using structured questionnaires. The type of tobacco product(s) used, daily amount of tobacco consumed, duration of use, and age of initiation to tobacco were also reported. Using the Fagerström test, nicotine dependence was determined and intent to quit use of tobacco products was described. Data on any other substance use, such as alcohol, cannabis and khat, including duration of use, were also collected. Psychiatric diagnoses were abstracted from participants' files. Participants' health-related quality of life was assessed using the World Health Organization (WHO) Quality of Life Brief Questionnaire at baseline and at 24 weeks follow-up[21].

Statistical 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 interquartile ranges, where appropriate. Bivariate analyses were carried out to compare the intervention groups with the control groups with respect to sociodemographic characteristics, history of tobacco and substance abuse, type(s) of mental illness, and HRQOL scores at baseline and at follow-up. Mann-Whitney tests were used to compare the intervention and control groups for continuous variables, and chi-squared tests were used for categorical variables.

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 HRQOL from baseline to follow-up at 24 weeks. 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.

RESULTS

Study participants

The flowchart of participants, including reasons for exclusion, is shown in Supplementary file Figure 1. Among the 105 participants who were screened, 97 participants were recruited: 49 participants were allocated to 1 of 5 intervention groups, and 48 were allocated to the control group. Over the 24-week study period, 35 participants were lost to follow-up, including 16 (32.7%) in the intervention group and 19 (39.6%) in the control group.

Participants' characteristics are shown in Table 1. 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 between groups. Mean (SD) age of participants was 35 (SD=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. At baseline, 15% had major depression, 7% had schizophrenia, and 9% had bipolar disorder. Most participants (94%) reported using cigarettes, with only 4% using kuber. Characteristics comparing those who completed the study and those who did not, are reported in Supplementary file Table 2, which demonstrates the similarities between the two groups.

Primary outcome: tobacco cessation rate

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 2).

Secondary outcomes: reduction in tobacco consumption

When comparing the reduction in amount smoked at baseline to follow-up at 12 weeks and 24 weeks, the intervention group reduced the number of cigarettes or kuber smoked more than the control group at week 12 (mean: 3.42 (SD=3.52) sticks in the intervention group versus 11.65 (SD=5.77) sticks in the control group, p<0.001) and at week 24 (mean: 5.78 (SD=6.37) sticks in the intervention group versus 12.17 (SD=6.89) sticks in the control group, p<0.0001) (Table 3).

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[6,13]: 8 (6–13) cigarettes or kuber vs control group reduction 2 (-2–6), p<0.0001) (Supplementary file Table 3). 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 the group allocation and tobacco cessation[4], the direction and magnitude of effect were similar (HR=14.92; 95% CI: 4.06–54.86) (Table 4).

Secondary outcomes: health-related quality of life (HRQOL)

Mean HRQOL scores at baseline and follow-up at 24 weeks in the intervention and control groups are given in Table 5. When comparing the four domains in the instrument (i.e. physical, psychological, social relationships, and environment) at baseline and at the 24 weeks follow-up, changes at the 24 weeks follow-up were numerically higher in the intervention group compared to the control group. However, these differences were not statistically significant.

Changes in HRQOL in the intervention and control groups among individuals who completed the 24-week follow-up period are reported in Supplementary file Table 4. 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% CI: 1.79–19.03) domains (p<0.01 for both), but changes in other domains were similar between groups. Domain-specific, adjusted results are reported in Supplementary file Table 5, which show a similar direction to the overall results with better quality of life in the environment domain among individuals

Table 2. Successful cessation biochemically verified at 12 weeks and 24 weeks follow-up among trial participants

		Intervention (n=33)		Control (n=29)		
		n	%	n	%	p
Cessation at 12 weeks follow-up	No	28	84.8	34	100	0.02
	Yes	5	15.2	0	0.0	
Cessation at 24 weeks follow-up	No	30	90.9	29	100	0.10
	Yes	3	9.1	0	0.0	

Table 3. Amount smoked at baseline, at 12 weeks and at 24 weeks follow-up, among trial participants

Time point		Intervention	Control	p
Baseline				
Participants		49	48	
Number of sticks	Mean (SD)	12.88 (7.03)	13.96 (6.45)	0.43
	Median (IQR)	9 (8–16)	14 (9–16)	
At Week 12				
Participants		33	34	
Number of sticks	Mean (SD)	3.42 (3.52)	11.65 (5.77)	<0.0001
	Median (IQR)	2 (1–5)	11 (7–15)	
At Week 24				
Participants		33	29	
Number of sticks	Mean (SD)	5.78 (6.37)	12.17 (6.89)	<0.0001
	Median (IQR)	2 (1–10)	10 (7–16)	

Table 4. Cox proportional hazards regression models for the outcome of any reduction in smoking among trial participants

Covariates	HR	95% CI		AHR*	95% CI	
		Lower	Upper		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 (Male)	1.99	0.92	4.34	3.03	1.16	7.92
Baseline Fagerström score	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

*AHR: adjusted hazard ratio; 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.

Table 5. Mean changes in health-related quality of life (HRQOL) among the different domains at baseline and at end of 24 weeks study period among trial participants

Domains	Time point	Intervention		Control		Intervention vs control
		Mean (SD)	p	Mean (SD)	p	p
Physical	Baseline	12.99 (3.19)	0.12	14.51 (1.89)	0.47	0.004
	At 24 weeks follow-up	13.90 (2.71)		12.78 (2.61)		0.48
Psychological	Baseline	13.27 (2.83)	0.88	13.88 (2.39)	0.29	0.20
	At 24 weeks follow-up	13.62 (2.26)		12.56 (2.00)		0.24
Social relationships	Baseline	12.65 (3.51)	0.08	13.22 (2.98)	0.51	0.59
	At 24 weeks follow-up	12.81 (3.54)		11.51 (2.60)		0.15
Environment	Baseline	12.57 (3.18)	0.44	14.56 (3.46)	0.50	0.01
	At 24 weeks follow-up	13.24 (2.84)		11.94 (1.42)		0.20

randomized to the study intervention group (AOR=6.46; 95% CI: 1.79–23.34).

DISCUSSION

Summary of results

Using a controlled clinical trial design, the study sought to determine the efficacy of a group tobacco cessation behavioral intervention among tobacco using patients with concomitant mental illnesses in Kenya on tobacco cessation at follow-up at 24 weeks, and to evaluate the effect of a group tobacco cessation behavioral intervention on HRQOL 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 smoked, or kuber chewed, compared with the control group over the study period; 2) adjusted 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; and 3) intervention group participants reported greater change in HRQOL scores compared with control group participants, though these results were not statistically significant.

Explanation of results

There were a greater number of participants in the intervention group who achieved the primary outcome, which was statistically significant at the end of week 12, but was not statistically significant by the end of the study at 24 weeks. The results could be considered potentially clinically meaningful given the harmful health effects of even light smoking; however, because the study is underpowered to detect true differences, we report these results within this limitation. Similar to our findings, a study by Prochaska et al.[23] evaluated the effects of a motivational tobacco cessation treatment combined with nicotine replacement therapy compared to usual care initiated in inpatient psychiatry. The study showed that abstinence was significantly higher for the intervention group than usual care at 3 months (13.9%

vs 3.2%) and at 6 months (14.4% vs 6.5%) at 7-day point prevalence biochemically verified[22]. Due to the high loss to follow-up in this study, strategies to promote retention among study participants are key to better evaluate the intervention's effectiveness.

The study shows frequent quit attempts and reduced numbers of cigarettes smoked during each meeting. Participants were not told to stop tobacco use immediately, as the study did not offer nicotine replacement therapy. Gradual smoking reduction can decrease the severity of withdrawal and cravings compared with immediate cessation. Indeed, withdrawal symptoms and cravings are the main deterrents to achieving cessation and contributing to relapse[23], and has been shown to predict future abstinence in the schizophrenia population[24]. In cessation attempts, cutting down the number of daily cigarettes smoked may increase quit attempts while encouraging continued attempts and potentially increasing self-confidence and success. Higher confidence in one's cessation efforts are thought to increase the likelihood that a final goal – in this case cessation – will be achieved[25]. Successful smoking cessation is difficult, with as few as 3–5% successfully quitting without assistance, and less than 10% of all smokers who achieve long-term abstinence, succeed after many unsuccessful quit attempts[26].

Most participants were unable to sustain cessation at the end of the 24-week follow-up period. However, some participants were able to reduce the number of sticks they smoked (<2 sticks per day) with a higher rate in the intervention group. It may be possible that a longer period or more frequent doses of the group behavioral intervention may have been needed to achieve a higher cessation rate in these participants. 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.

Comparison with clinical guidelines and prior research

Clinical guidelines for tobacco cessation reported by Fiore et al.[27] recommend more intensive interventions as well as pharmacotherapy to improve cessation outcomes. The findings of this study suggest that counselling is feasible and potentially effective. Policies to improve availability, accessibility, and affordability of tobacco cessation pharmacotherapy, are needed to help Kenyan tobacco users with mental illness to quit. Aveyard and Linson-Hawley[28] noted that people who are reducing their tobacco consumption are more likely to attempt to quit and to succeed than those who are not. These authors identified a need to teach people methods to help them reduce tobacco consumption as a strategy to increase the likelihood of achieving successful cessation[28].

Results from de Leon et al.[29] showed that maintaining tobacco cessation among patients with concomitant mental illness is very difficult. The study, which focused on alcohol, drugs, and smoking cessation, found that almost half (45%) of people with severe psychiatric illness were able to quit alcohol or drugs, but only 10% successfully remained quit within a period of one year. This outcome was similar to our study, as 15% were able to successfully quit at the end of 12 weeks, but only 9% remained successfully quit at the end of the 24-week study period. People with mental illness mostly have poor outcomes with cessation treatments; there is a need to develop new interventions specifically focused for this population.

The SCIMITAR study, which was a tobacco cessation intervention incorporating behavioral support and pharmacological aid among persons with mental illness, showed the proportion of participants who quit at 6 months was significantly higher in the intervention group than the control group (14% vs 6%, p=0.01). Despite our study not offering pharmacological support, it offered the 'cut-down' to quit approach similar to the SCIMITAR trial. The SCIMITAR investigators observed an improvement in physical health in the intervention group at 6 months; however, this difference was no longer evident at 12 months. On the other hand, there was no difference in mental health domains among SCIMITAR participants at 6 months and at 12 months[30].

Results from eight clinical trials with treatment periods lasting 8 to 12 weeks started in inpatient settings and continued post discharge, have shown smoking quit rates of different cessation intervention, including behavioral and pharmacological interventions, range from 4% to 22% among people with mental illnesses[31]. Banham et al.[32] reviewed 8 randomized controlled trials and found similar results to the current study. They found that none of the trials reviewed reported any significant differences between intervention and control groups at the end of follow-up; however, these randomized controlled trials (RCTs) all incorporated nicotine replacement therapy in their interventions. No significant differences were reported between a specialized severe mental illness smoking program with NRT compared with standard smoking cessation group therapy with NRT, at either end of trial or end of follow-up (one RCT). The review reported greater abstinence rates at trial end for: individual therapy together with NRT compared with usual care (RR=2.74; 95% CI: 1.10–6.81; one RCT); bupropion together with group therapy compared with placebo with group therapy (RR=4.18; 95% CI:1.3–013.42; three RCTs); bupropion together with group therapy and nicotine replacement therapy compared with placebo; and group therapy and NRT (RR=2.34; 95% CI: 1.12–4.91; two RCTs).

The current study also showed that tobacco cessation improves health-related quality of life which is congruent with prior research. In a cross-sectional study exploring the association between smoking and health-related quality of life among smokers in China, smoking was inversely associated with quality of life, the average probability of having a higher quality of life was 11.7% lower among individuals who smoked compared with those who did not

smoke[33].

Most of these RCTs had findings almost similar to our study even though most of them incorporated cessation pharmacotherapies. This shows that our study has promise of increased positive outcomes, particularly if pharmacotherapies are included.

Strengths and limitations

This study has several strengths. First, the study was conducted among a high-burden population in a novel setting and was implemented in participants' usual environments and during regularly scheduled outpatient clinic follow-up days. 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 demonstrated feasibility, acceptability, and a signal of benefit from the intervention, suggesting potential benefits with further refinement.

The current study also had important limitations which may influence the certainty of the findings. First, 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 generally accurate, unless the participants fear loss of particular benefits if they do not quit[34]. To reduce the risk of ascertainment bias, biochemical verification was conducted on participants who reported complete cessation.

Second, by design, the intervention group met more frequently compared to the control group. Participants may have benefited from the study intervention but may have also been susceptible to the Hawthorne effect, wherein their behavior changed because of the process of observing the behaviour[35]. 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.

Third, the study had a high loss rate to follow-up and we treated 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[36]. The research team tried to contact all participants who were missing before group meetings began. When a participant failed to attend meetings three consecutive times, they were counted as having dropped out (lost to follow-up). It may be possible that some participants who dropped out were misclassified as continuing to use tobacco. However, this is likely to be uncommon and would not materially influence the overall direction and magnitude of effect.

Higher retention may have led to a larger effect than was observed, though it may be possible that the opposite effect is also true. Fourth, the study did not analyze the actual cost of the intervention. Knowing the actual cost might help with implementation and replication in different mental healthcare facilities.

CONCLUSIONS

Results from this trial demonstrate feasibility and benefits of a tailored group tobacco behavioral tobacco cessation intervention among mentally ill population with tobacco use dependence in Kenya. This study showed that persons with mental illness are willing to quit tobacco use and to engage in tobacco-related research. Results also suggest that these individuals can reduce the number of cigarettes used and can improve their health-related quality of life through a group behavioral intervention, even without cessation pharmacotherapies. Future research should evaluate adaptations of the current study to improve retention for longer term effects across a larger, more diverse population in Kenya, and other Sub-Saharan African countries.

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DATA AVAILABILITY
The data supporting this research are available from the authors on reasonable request.

AUTHORS' CONTRIBUTIONS
YO was the principal investigator of the study and designed the implementation. MK, MM and MDH reviewed the proposal, data collection tools and procedures, and the manuscript. YO took part in the data collection. FN and MK analyzed the data. This manuscript was written by YO, with input from all co-authors who provided critical revisions. All authors have read and approved the final manuscript.

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