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The budget impact analysis of nicotine replacement therapy among patients who smoke tobacco and have mental illness in South Africa and the implications

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Abstract

Background Tobacco use is the world's leading preventable cause of death, with the highest burden in low and middle-income countries (LMICs). Those who have mental illness are particularly vulnerable, with a smoking rate two to five times higher than that of the general population. Quitting smoking has demonstrated benefits for mental health, including reducing stress and improving the quality of life. However, the economic feasibility of introducing Nicotine Replacement Therapy (NRT) in the psychiatric medical environment in South Africa has not yet been explored. This study aims to address this gap by assessing the impact on the budget of implementing an NRT-based smoking cessation program in a psychiatric hospital.

Methods This retrospective and cross-sectional study followed a budget impact analysis framework. Data were retrieved between May 19 and Aug 18, 2023, from 214 patients' medical records. Using primary and secondary data, an ingredients costing approach was used to estimate direct treatment costs of NRT smoking cessation. All costs were expressed in ZAR (South African currency). The economic evaluation was conducted from the payer's perspective, and the results were reported at a 5% discount rate. A two-way 10% sensitivity analysis was conducted.

Results The study showed that study participants were primarily black, male, unemployed, diagnosed with schizophrenia and smoked lightly (69.16% ±3.46). Implementing the 3-month treatment period of NRT smoking cessation program would result in an expenditure of R1 478 915.42 for 214 patients. The hospital will require an additional 0.15% (±0.0095) of the total hospital budget and 6.09% (±0.31) of the hospital pharmacy budget.

Conclusion Our findings indicate that while implementing a NRT is crucial for improving the overall health outcomes among patients with mental illnesses, substantial investment would be required. The budgetary allocation for NRT smoking cessation interventions would vary by treatment settings and program duration. Consequently, careful consideration of budget allocation and resource distribution is necessary to ensure the program's sustainability within the broader healthcare framework in South Africa.

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Keywords Budget impact analysis, Smoking cessation, Nicotine replacement therapy, Mental health, Psychiatric hospitals, South Africa

Introduction

Tobacco use remains the single most avoidable cause of death globally and a critical public health issue, killing over 8 million people a year, including 1.3 million of individuals who do not use tobacco, with the highest mortality seen in low and middle-income countries (LMICs) [1, 2]. Smoking is currently acknowledged to be a leading risk factor for increased mortality among males, as well as causing considerable morbidity, with an estimated 200 million disability-adjusted life-years (DALYs) globally in 2019 [3]. In South Africa, the prevalence of smoking among adults was 29.4% in 2021, an increase from 25% in 1998 [4, 5]. Consequently, smoking was and remains a critical public health concern, particularly among individuals with mental health conditions, who are disproportionately affected [6–8].

Globally, individuals with mental health conditions are estimated to be two to five times higher among patients with schizophrenia, mood disorders, anxiety disorders, attention-deficit/hyperactivity disorder (ADHD), and substance use disorders than in the general population [6–9], impacting on tobacco use. In the United States, adults with mental illness had a higher prevalence of smoking (33.3%) compared to those without mental illness (20.7%) [10]. Similarly, in Brazil, the prevalence of current tobacco use was 53% among individuals with mental illness, markedly higher than the 18% reported in the general population [11]. South Africa exhibits similar differences between the populations with individuals with mental health conditions consistently exhibiting appreciably higher tobacco use rates compared to the national average [12, 13] with cigarette smoking in South Africa significantly associated with incidents of depression [14].

In 2021, tobacco use varied across provinces, with Eastern Cape at 29.2%, Gauteng at 23.1%, Free State at 30.8%, KwaZulu-Natal at 21.7%, Western Cape at 36.9%, and Northern Cape at 42.3% [5]). Notably, in the Eastern Cape, individuals with mental illness exhibited a significantly higher prevalence of lifetime tobacco use (54.9%) and current use (44.6%) [15], appreciably higher than the rates found in the general population in the region (15%) and the country (17.6%) [13, 15, 16]. This is because smoking is seen as a coping mechanism to relieve symptoms including stress, anxiety, and difficulty concentrating, with adults with depression twice as likely to smoke as those without depression [17]. As a result, highlighting a concerning link between mental illness and tobacco consumption [15],

A key strategy to improve smoking cessation rates is nicotine replacement therapy (NRT), which reduces symptoms of nicotine withdrawal and supports the transition to complete cessation [18]. Overall, NRT increases the likelihood of smoking cessation by 50–70% compared with attempts to stop smoking without therapy [18–20]. Behavioral support, combined with NRT, further increases quitting rates [21]. Studies have shown the effectiveness and cost-effectiveness of NRT-based interventions, with significant benefits observed among different populations [22–26]. However, limited research has explored the financial and logistical feasibility of the implementation of NRT in psychiatric settings in South Africa. This is important since a recent study conducted in South Africa showed that 92.1% of the participants in an online survey were aware of NRT and among those intending to quit, two-thirds indicated a desire to use a cessation aid such as NRT [4].

The cost dynamics of smoking cessation programmes do vary depending on country and type of treatment. Research in Europe, the United States and Brazil has shown that, despite the dominance of pharmaceutical costs in the implementation budget, these programmes often save costs over time due to lower overall health costs [17, 27, 28]. For example, a 12-week smoking cessation programme in Italy revealed that the cost of medicine accounted for 88.95% of total costs, but that the program achieved cost savings in the fourth year [29]. In South Africa, the resource constraints of public health systems require a careful consideration of the economic viability of such programs.

Studies undertaken across countries have shown that NRT-based interventions are cost-effective and potentially cost saving [30, 31]. However, limited research has focused on their financial and logistical feasibility in South African psychiatric settings. This study aims to address this gap by assessing the cost of implementing a NRT program in South African psychiatric hospital and to provide important insights for future policies and decisions addressing this high-risk populations.

Methods

Study design

This study was a retrospective, cross-sectional, and economic evaluation reported using the CHEERS 2 checklist [32, 33]. A Budget Impact Analysis (BIA) was conducted from the payer's perspective to help maximize health outcomes within given budgets, similar to previous BIAs conducted by some co-authors [34–36]. A BIA is a method of synthesis of existing knowledge at the

time of a policy to estimate the potential financial consequences of that decision for a health system [37]. The BIAs are seen as crucial components of a comprehensive economic analysis as they are used to calculate current expenditures in particular disease areas and the expected change in expenditures to a particular budget holder as a consequence of their decision to pay for new healthcare interventions or other policy modifications [33–36]. However, there can be concerns and conflicts of interest depending on the study's sponsor [37].

The BIA for this study was conducted in Microsoft Excel following the National Institute for Health and Care Excellence (NICE) budget template as well as the Professional Society for Health Economics and Outcomes Research (ISPOR) suggestions to standardize the BIA process [37]. Our analysis made a comparison in cost differences between the current situation of no intervention for smoking cessation and a new intervention of introducing an NRT in psychiatric hospitals dealing with both in and outpatients. South Africa, like many low-and middle-income countries (LMICs), lacks standardized frameworks or guidelines specifically tailored for conducting economic evaluations of smoking cessation programs. This gap necessitates the adoption of established international standards to ensure methodological rigor and comparability with global studies.

The National Institute for health and Care Excellence (NICE) in the UK provides a comprehensive BIA template that is widely recognized for its structured approach to estimating the financial implications of implementing healthcare interventions. Similarly, ISPOR offers globally accepted recommendations for conducting BIAs. This study ensures a robust and standardized economic evaluation by utilizing the NICE budget template and aligning with ISPOR methodological suggestions. This approach compensates for the absence of national standards and facilitates the possible generation of evidence that can inform policy decisions within South Africa's healthcare context while being internationally comparable.

The NICE and ISPOR frameworks were contextualized in the context of South Africa by adapting their methods to the realities of the local health system, including central drug procurement, budgetary restrictions and the high burden of smoking-related diseases in psychiatric settings. Local data such as epidemiological and cost-specific information for South Africa have been included to ensure their relevance, and equity considerations are addressing the disproportionate effects of tobacco use on mental health patients. The frameworks were further adapted to consider the feasibility of implementation in resources-limited psychiatric environments, and the limitations of health workers. These contextualization's ensured that the economic assessment was in line with the unique characteristics and priorities of the public health sector in South Africa.

Study site

This study was conducted at a 974-bed psychiatric tertiary referral hospital in the Pretoria West region in Gauteng Province, South Africa. The hospital provides mental health care services to outpatients and inpatients and is a designated smoke-free hospital. This site was conveniently selected for this study due to NRT patches being proposed for mentally ill inpatients with concerns about smoking in this clinical setting. This is because, despite an official smoking cessation policy suggested by the Gauteng Department of Health, this service delivery has yet to be implemented in this hospital. The data were extracted from inpatient files of adult mental health care users (MHCU) who are tobacco product users.

Target population

The study population included all the adult inpatients in the psychiatric hospital who were eligible to receive NRT patches as part of their therapy. Using Epi Info (Centres for Disease Control and Prevention, Atlanta, United States of America), assuming an expected frequency of 50% to give the largest sample size at 80% power and 95% confidence level, the sample size required was 275. The final sample size for this study was 214 participants, which included 148 patients who smoked lightly and 66 patients who smoked heavily The study excluded inpatient files of MHCUs who were not prescribed NRT patches, who did not smoke, those who were prescribed NRT patches after the data collection period, and all outpatients. Currently, there is no standard therapy for smoking cessation at the hospital; consequently, the intervention with NRT was compared to a null scenario.

Data collection

Convenient sampling was used to select patient files from the psychiatric hospital. Files of patients who were admitted to the hospital, who were users of tobacco, regardless of the diagnosis, were reviewed from each ward in the hospital from May 19, 2023, to Aug 18, 2023. The researcher used a carefully designed data collection tool to collect data. The principal researcher (BM) used the data collection tool to extract data on the number of cigarettes patients smoked per day among the inpatients, categorizing them into patients were lightly smokers and those who smoke heavily user. In addition, sociodemographic data, diagnosis, and direct costs were collected over 3 months. Non-medicine-related treatment costs, including hospital personnel wages, were extrapolated from published data based on the average time for doctor consultations, pharmacist-dispensing of, and nurse administration of NRT patches as primary data

was unavailable. Patient files were kept in the file room in each ward. The researcher went through all the files in each ward in the filing order that the wards used to ensure that all files were accounted for.

Data analysis

The researchers used the recommended treatment in the Leeds Teaching Hospitals Pharmacy Services guidance to classify treatment protocols for the different categories [38]. This treatment protocol was selected to model the treatment pathway of patients in this study because it comprises the same NRT patch strengths available in South Africa and the proposed NRT patches from the local supplier [39]. The same NRT patch strengths were also selected as they aligned with the South African Medical Formulary, version 14 [40]. The model inputs drug and treatment-related costs, which were calculated using the ingredients costing and BIA. Based on the information retrieved from patient files, patients who smoked lightly or patients that smoked heavily, i.e. frequently, were categorized as follows in line with published studies [41–43]:

- patients that smoked heavily : smoke 10 or more cigarettes a day.
- patients that smoke lightly : smoke 1–9 cigarettes a day.

As per the Leeds treatment protocol [39], smokers who smoked heavily were treated with a 25 mg NRT patch (Nicorette®) for 8 weeks, 15 mg for 2 weeks, and 10 mg for 2 weeks. Those who smoked lightly were treated with the 15 mg NRT patch for 8 weeks and with the 10 mg patch for 4 weeks.

The cost of the current or new intervention mix was determined by multiplying the procurement costs for each intervention by the proportion of the eligible population using that intervention. The costs for those who smoked heavily or lightly were subsequently added together to give the cost of treatment by implementing a NRT smoking cessation policy and comparing them to the budget allocated to the pharmacy to determine the impact. The 3-monthly costs for implementation of the NRT program were extrapolated to one year to project the costs required to run the program for a year with different inpatients or those who failed to quit smoking in the first treatment program. The costs were also extrapolated to a year to estimate the program's costs over 5 years.

Estimated treatment-related cost analysis

Drug-related costs included resource utilization, doctors, pharmacy personnel, nurses, administrative staff, transdermal patches, gloves, and alcohol swabs. The average time was equated to South African Rands (ZAR) using employees' annual salaries. The time of doctor consultations was extracted from several published studies, including Ahmad et al., Gray and Orton, and Lee et al., as no robust data was available for South Africa [44–47]. It was assumed that the initial consultation with physicians would take twice the follow-up sessions at just over 32 min to establish the patient's history and the optimal treatment plan. After this, consultations were assumed to take just over 16 min and 13 s, as averaged from published studies. The time spent with nurses for the administration of the NRT patches was also averaged from published studies, including those of Thomson et al. (2009), Barker et al. (2017), and Yen et al. [48–50]. The time of dispensing by pharmacists was also extracted from published studies, including those by Mathew et al., Sun et al., and Chand et al. [51–53]. The salaries were extracted from the Gauteng Department of Health vacancy website [54]. The salaries per year allowed the determination of the average cost per hour. Overall, it was calculated that the costs for the first consultation with the doctor and nurse were R214.06 and R52.74, respectively. The remaining 11 sessions with the Dr and 83 with the nurse were R107.03 and R26.37 each. The gloves and alcohol samples have been included as part of standard infection control procedures during the application of NRT patches by medical personnel.

Even though labour in the South African healthcare system is not renumerated on a patient basis, incorporation of labour costs into our analysis is crucial given the major challenges facing South Africa's healthcare workforce. The country is expected to experience a shortage of about 97,000 qualified health professionals by 2025, which is further exacerbated by budgetary constraints and frozen positions within the Department of Health [55, 56]. This has resulted in limited employment opportunities for newly qualified doctors and other medical professionals [55, 56]. Given these constraints, integrating NRT smoking cessation interventions or any other programme regarded as new requires additional time and effort from healthcare providers. As a result, accounting for labour costs provides a more comprehensive understanding of the resources needed for such interventions and highlights the need for strategic planning to ensure their successful implementation.

It was assumed that pharmacy dispensing time would be just over 8 min 17 s, average from studies by Mathew et al., Sun et al., and Chand et al. [51–53]. All 12 pharmacist dispensing sessions were calculated at R35.87 each. The costs were converted using the average 2023 exchange rate of $1 to R18.55, £1 to R22.97, and CHF1 to R20.56 (Xe Currency Converter - https://www.xe.com/currencyconverter/). It is also assumed that patients will remain hospitalized for the 3-month treatment duration

and do not abruptly remove the patches and follow the correct treatment regimen.

The cost of the miscellaneous items (gloves and alcohol swabs) was obtained from Government contracts expressed in ZAR. The prices of the NRT patches were sourced from the public hospital's contracted supplier, Johnson and Johnson Services Inc., and were R206.74 (May 2023) regardless of the strength of the patch. The gloves cost R144.90 for a pack size of 100 gloves (May 2023), and the alcohol swabs cost R24.95 for a pack size of 40 alcohol swabs (May 2023).

Costs were subsequently discounted using a 5% discount rate [57].

$$\text{Formula: Cost over 1 year X } (1+\text{Y})^{\text{n}}$$

Y = discount rate.
n = number of years of projected BIA.

Uncertainty and sensitivity analysis

The uncertainty of the assumptions made was tested using sensitivity analysis. The analysis varied the population size, cost of healthcare personnel, time it took for each session with healthcare personnel, and non-compliance with the treatment course.

A two-way sensitivity analysis was performed to test the robustness of the parameters for the economic evaluation, which included the time spent by doctors, nurses, and pharmacists on the NRT smoking cessation program. The variables were reduced by 10% and increased by 10% to see how the change in variables affects treatment and treatment-related costs.

Results

Patient demographics

Medical records were retrieved for 214 participants, with the majority being male (94.86% ±4.74) and black (82.71% ±4.13). Most participants were single (91.12%), and the highest level of education obtained was Grade 7 to Grade 12 (40.19% ±2.01). All 214 participants were unemployed. The majority (71.03% ±3.55) of patients were diagnosed with Schizophrenia (Table 1). There were more light smokers (69.16% ±3.46) than heavy smokers (30.84% ±1.54).

Table 1 Patient demographics

	Count	Percentage (%)
Number of participants(*n* = 214)		
Male	203	94.86
Female	11	5.14
Ethnicity (*n* = 214)		
Black	177	82.71
White	32	14.95
Indian	3	1.40
Colored	2	0.94
Relationship status (*n* = 214)		
Married	5	2.34
In a relationship	4	1.87
Single	195	91.12
Divorced	4	1.87
Missing information	6	2.8
Level of education (*n* = 214)		
No education	3	1.40
Gr 1 – Gr 7	32	14.95
Gr 8 – Gr 12	86	40.19
Tertiary education	4	1.87
Missing information	89	41.59
Diagnosis (*n* = 214)		
Schizophrenia	152	71.03
Substance-induced psychosis	31	14.49
Bipolar mood disorder	13	6.07
Intellectual disability	11	5.14
Major neurocognitive disorder	6	2.80
Antisocial personality disorder	3	1.40

Direct costs of treatment over 3 months

Medical records showed that between May 19, 2023, and August 18, 2023, there were 66 heavy smokers and 148 light smokers. Table 2 presents the direct medical costs of treating patients who were heavily smokers and who were lightly smokers, respectively.

The 25 mg patches are used for patients who heavily smoked tobacco for 56 days, and a treatment course costs R1 653.68± 82.68 per patient. Then followed by 15 mg and 10 mg NRT patches for 7 days, costing R413.42 (± 20.67) for each treatment course (Table 2). The direct medical cost (NRT patches) of treating either patients who heavily or lightly smoked tobacco for the 3-month treatment period was estimated at R2,776.20 (± 138.81). The direct medical costs (NRT patches) of the 66 patients who heavily smoked tobacco were estimated to be R183 229.20 (± 9 161.46) (Table 2) and R410 877.60 (± 20 543.88) for the 148 of patients who lightly smoked tobacco (Table 2). Of the total implementation costs, the direct costs for patients who heavily smoked tobacco was 10.15% (± 0.51) and 22.77% (± 1.1) for patients who lightly smoked tobacco, respectively.

Healthcare professional costs

Table 3 details the time and cost of each healthcare professional (HCP) consultation. Treatment of one patient for three months is estimated to cost R4 134.83 (± 206.74), and treating 214 patients will cost R884 853.62 (± 44 242.68) (Table 3). Since the target population is inpatients, no transportation costs have been included.

Table 2 Direct cost for patients who were heavy and light tobacco smokers for the 3-month treatment period, excluding healthcare professional costs

Patients who heavily Smoked tobaccos	Pack size	Cost (Rands)	Unitprice (Rands)	Treatment duration (Days)	Total (Rands) per patient	Proportion of costs to total costs (%)
Nicotine patches 25 mg	7	206.74	29.53	56	1 653.68(±82.68)	66.66
Nicotine patches 15 mg	7	206.74	29.53	14	413.42 (±20.67)	16.67
Nicotine patches 10 mg	7	206.74	29.53	14	413.42 (±20.67)	16.67
Gloves	100	144.90	1.45	2 gloves per session (168)	243.60 (±12.18)	82.39
Alcohol swab	40	24.95	0.62	1 alcohol swab per session 84	52.08 (±2.60)	17.61
Total					**2 776.20** (±138.81)	**100**
A total of 66 patients					**183 229.20** (±9161.46)	**-**
Patients who lightly smoked + tobacco	**Pack size**	**Cost (Rands)**	**Unitprice (Rands)**	**Treatment duration (Days)**	**Total (Rands)**	**Proportion of costs to total costs (%)**
Nicotine patches 25 mg	7	206.74	29.53	0	0	0
Nicotine patches 15 mg	7	206.74	29.53	56	1653.68 (±82.68)	66.67
Nicotine patches 10 mg	7	206.74	29.53	28	826.84 (±41.34)	33.33
Gloves	100	144.90	1.45	2 gloves per session (168)	243.60 (±12.18)	82.39
Alcohol swab	40	24.95	0.62	1 alcohol swab per session (84)	52.08 (±2.60)	17.61
Total					**2776.20** (±138.81)	**100**
A total of 148 patients					**410 877.60** (±20 543.88)	**-**

Table 3 Healthcare professional costs per patient

Fixed costs	Consultation Time	Cost per patient (CPS) (Rands)	Number of consultations	Cost of consultations (Rands) per patient	Proportion of costs to total costs (%)
First Doctors' Consultation	34 min 16 seconds	224.62 (±11.23)	1	224.62 (±11.23)	5.44
First Nurse Administration	21 min 12 seconds	52.16 (±2.61)	1	52.16 (±2.61)	1.27
Doctor (Excluding the first consultation)	17 min 8 s	112.31 (±5.62)	11	1 235.41 (±61.77)	29.88
Pharmacist	9 min 8 s	39.55 (±1.78)	12	474.60 (±23.73)	11.46
Nursing (Excluding the first consultation)	10 min 36 s	25.88 (±1.29)	83	2 148.04 (107.40)	51.95
Total				**4 134.83** (±206.74)	**100**
A total of 214 patients				**884 853.62** (±44 242.68)	**-**

Total costs of intervention

The NRT smoking cessation program would cost approximately R1.8 million for the 214 patients. The highest costs was attributed to nursing fees at R470 842.80 (±23 542.14), followed by the NRT patches for individuals who lightly smoked tobacco at R367 166.96 (±18 358.35) (Table 4).

Budget impact of the smoking cessation program and sensitivity analysis

For the sensitivity analysis, the variables were reduced by 10% and increased by 10% to see how the change in variables affects the population size, cost of healthcare personnel, the time it took for each session with healthcare personnel, and non-compliance to treatment course

Table 4 Total costs of the new treatment intervention for 214 patients over the 3-month treatment period

	Patients who heavilyy smoked tobacco (Rands) (*n* = 66)	Patients who heavilyy lightily smoked tobacco (Rands) (*n* = 148)
NRT Patches	163 714.32 (±8 185.72)	367 116.96 (±18 355.848)
Gloves	16 077.60 (±803.88)	36 052.80 (±1 802.64)
Alcohol swabs	3 437.28 (±171.86)	7 707.84 (±385.39)
Doctor fee	96 316.98 (±4 815.980	216 084.44 (±10 804.22)
Pharmacist fee	31 323.60 (±1 566.18)	70 240.80 (±1566.188)
Nursing fee	145 213.20 (±7 260.66)	325 629.60 (±16 281.48)
Subtotal	**456 082.98** (±22 804.150	**1 022 832.44** (±67 423.10)
Total	**1 478 915.42** (±90 227.25)	

(Fig. 1). The nurse consultation fee remains the highest cost driver, followed by patients who lightly smoked tobacco and then the NRT patches (Fig. 1). The sensitivity analysis shows that of the total cost of implementation, healthcare labor costs (R884 808.62) are the highest cost driver of our NRT smoking cessation program. The doctor's first consultation fees, the effect the cost of the doctor's first consultation time consultation, the nurse's first consultation fee, the effect cost of nurses' administration time excluding the first consultation, and the NRT patched for patients who lightly smoked tobacco are the five variables that influence the costs the most in the sensitivity analysis (Fig. 1). The NRT patches are the lowest cost-driver (R530 813.28). When the population is increased by 10%, there is an R185 000 increase in the total cost of implementing the NRT smoking cessation programme. The inflation and deflation of the variables by 10% still produce findings equivalent to the original treatment costs.

Discounting rate

The cost of implementing the NRT smoking cessation programme will be R7 550 049.93 (± 377 502.50), based on the 5% discounting rate (Table 5).

$$\text{Formula: Cost over 1 year X } (1+Y)^{n}$$

Y = discount rate
n = number of years of projected BIA.

Discussion

We believe this study is the first of its kind to be conducted in South Africa to assess the budgetary impact of implementing a NRT program among smokers with mental illness in the country. This research was conducted to address the gap in the understanding of the financial and logistical requirements with implementing a smoking cessation program, specifically focusing on NRT, in a psychiatric hospital setting, given ongoing concerns with implementation of Government activities banning smoking [56]. The study showed that study participants were primarily black, male, unemployed, single, light smokers (69.16% ±3.46) and diagnosed with schizophrenia. Initiating the 3-month treatment period with NRT would result in an expenditure of R1 478 915.42 for 214 patients. The hospital will require an additional 0.15% (± 0.0095) of the total hospital budget and 6.09% (± 0.31) of the hospital pharmacy budget.

This is because the average budget impact of the 12-week treatment course for both light and heavy smokers in the NRT program was R4 134.83 per patient. However, the total cost proportion for treating those who smoked lightly was higher than for those who smoked heavily, reflecting a more significant proportion of light smokers. This is similar to other studies where there were more smokers who smoked lightly compared with those who than smoked heavily [32, 58, 59]. The more significant proportion of light smokers in our study may reflect the fact that some inpatients had been weaned off smoking or reduced their smoking habits at the time of data collection, resulting in most of the participants in our study being light smokers (69.16%) with an average of nine (09) cigarettes smoked per person per day. However, further research is required to validate our findings.

The budget impact costs of implementing the NRT smoking cessation program in our study were 30.39% for NRT patches and 59.84% for healthcare labor costs. This is similar to other studies where labor costs were the dominant cost driver, including those in Brazil (73.1%), the USA (67.4%), and Switzerland (81.8%) [28, 60, 61]. Cele et al. [62] also found that among South African primary healthcare settings, NRT and pharmacotherapy were the highest cost drivers, comprising more than 70% of total costs [63]. However, whilst Levy et al. in the USA also found that staff supervision costs accounted for an appreciable proportion of overall costs in their intensive smoking cessation program (26%), other cost items were also significant, including treatment costs (35%) and

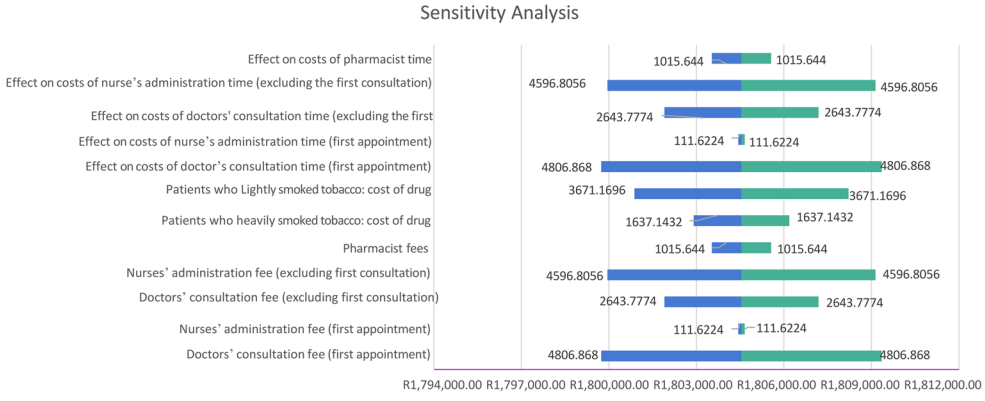

Fig. 1 Sensitivity Analysis

Table 5 5-year budget impact. The discount rate used is 5%

	3 Months	Current Year 1 (2023)	Year 2	Year 3	Year 4	Year 5
Drug costs (Rands)	530 831.28 (± 26 541.56)	2 123 325.12 (± 106 166.26)	2 340 965.94 (± 117 048.30)	2 458 014.24 (± 122 900.71)	2 580 914.95 (± 129 045.75)	2 709 960.70 (± 135 498.04)
Treatment-related costs (Rands)	1 273 713.74 (± 63 685.69)	3 792 336.56 (± 254 742.75)	4 181 051.06 (± 209 052.55)	4 390 103.61 (± 219 505.18)	4 609 608.79 (± 230 480.44)	4 840 089.23 (± 242 004.46)
Total Cost(Rands)	1 478 915.42 (± 90 227.25)	5 915 661.68 (± 360 909.00)	6 522 017.00 (± 326 100.85)	6 848 117.85 (± 342 405.89)	7 190 823.74 (± 359 541.19)	7 550 049.93 (± 377 502.50)

Treatment-related costs include personnel costs and the cost of miscellaneous items(alcohol swabs and gloves)

NB Drug costs include the cost of NRT patches

patient enrollment costs (24%) [32]. These differences may reflect the differences in the intensity of the counseling and the cost of treatment.

The estimated 2-week cost for NRT patches in our study was R413.48. Comparatively, studies by Chen et al. reported a cost of $37.50 (R665.22), and Krupski et al. noted a cost of $21 (R372.52) for a 2-week NRT patches supply [31, 64]. The cost variability between the studies is substantial and must be considered carefully in any BIA. In addition, benchmark figures for health authorities to assess the payments they make for pharmaceuticals should be provided, similar to other benchmark studies across countries, including among African countries [65, 66]. For instance, in South Africa, because the centralized procurement system, tender pricing can result in cost savings of up to 30%–50 and consistent among provinces [67]. However, given the US health landscape, it is likely that cost estimates are derived from standard market prices, hence, variability in costs of NRT patches among studies [31, 64, 68].

Most participants in the study were black (82.71%). Studies have shown that tobacco corporations target black communities with their advertising and that the treatment effects of smoking cessation interventions are weaker for blacks than for whites [59]. There are significant price reductions on tobacco products in areas where black people make up a more significant percentage of the population, and businesses have increased the amount of shelf space for tobacco products in these communities [59]. The unique challenges faced by black communities necessitate tailored smoking cessation interventions that consider the social determinants of health, structural inequities, and cultural contexts. This includes developing strategies to counter targeted marketing, ensuring equitable access to cessation resources, and addressing the specific barriers to effective treatment in these communities.

Most of the participants in our study suffered from schizophrenia and psychosis, similar to a Canadian study which highlighted that tobacco smoking rates in patients with schizophrenia ranged from 45 to 88% [60]. Other studies from the USA, UK, and Australia echoed similar results that the smoking rate of outpatients with schizophrenia, bipolar disorders, and post-traumatic stress disorder (PTSD) is 18% for those without a mental disease. In comparison, it is 61% for those with three or more mental illnesses [59, 61]. These factors highlight the need for mental health-specific smoking cessation strategies that balance therapeutic goals with effective tobacco control measures.

However, a current concern in South Africa is that access to quality mental healthcare remains uneven within the public sector, and starkly contrasts with the private healthcare system, where approximately 80% of psychiatrists are concentrated [69, 70]. The mental health treatment gap in sub-Saharan Africa is exacerbated by a scarcity of skilled professionals, inequitable resource distribution, and persistent stigma surrounding mental illness. A national survey on South Africa's public mental health expenditure revealed that, in the 2016/17 financial year, USD 615.3 million (5.0%) of the total public health budget) was allocated to mental health services, equating to USD 13.3 per uninsured capita [69]. Inpatient care accounted for 86% of the expenditure, nearly half of the total at the psychiatric hospital level [69]. This needs to be addressed with currently many people in South Africa with mental illness going untreated with the lack of mental health care providers [70, 71]. There is also a lack of funding and resources for the primary and community-based mental health treatment system, compounded by persistent scarcity of skilled human resources, significant inequities, and inefficiencies in resource distribution [69–71]. Consequently, there is a need to scale up evidence-based services to affirm task-shifting of mental health interventions to non-specialists as key strategies for closing the treatment gap [70]. Another way forward is through Mental Health integration (MHI). This is where smoking cessation programs can be part of mental health services. South Africa can develop guidelines for dual diagnosis of mental healthcare conditions and smoking. In this way, the healthcare providers can treat more than one condition. This theory may need to be tested as the consultation time may still need to be extended. We will continue to monitor the situation.

We are aware this study has several limitations. Firstly, the associated times for doctors, nurses, and pharmacists were extracted from international literature as there is no available data for doctor and nursing consultation times and pharmacist dispensing times in South Africa. Secondly, patients were also assumed to comply, and not remove, their NRT patches before the completing the treatment course (3 months). Adding more patches would increase these costs. Thirdly, we only conducted the study in one hospital. Incorporating additional hospitals and patients would enhance the robustness of our findings since the required sample size ($n = 275$ patients) was not met due to some active smokers being weaned off smoking between the time of the protocol write-up and data collection. This resulted in fewer patients who smoked tobacco during data collection and a lower documented number of cigarettes smoked, affecting the numbers of the higher smokers for categorization. Fourthly, convenient sampling limits the generalizability of our findings to other hospitals with different population characteristics and policy strategies. Furthermore, only files of patients who were admitted at the time of data collection with complete medical records were included in the study. Lastly, the study made use of self-reported

data (number of cigarettes smoked per day); consequently, there may be recall bias when patients were asked the number of cigarettes they smoked on average each day. In addition, the smoking cessation program was evaluated as vertical care and not integrated with mental health care services. However, despite these limitations, we believe our findings will be of interest to the authorities in South Africa as they seek to reduce smoking rates and associated morbidity and mortality.

Conclusion

The study highlights the significant financial and logistical requirements for the implementation of NRT programs among patients with mental health conditions and smoking within the inpatient setting in South Africa. The results emphasize the importance of specific strategies to address demographic problems and integrate smoking cessation programs into existing mental health services. Whilst the financial investment need for the implementation of NRT approaches is considerable in this population, we believe the potential benefits – including reducing morbidity and improving the quality of life – justify such initiatives. Future research should focus on multi-site studies and explore the integration of cessation programmes with broader frameworks for mental health care in order to improve both feasibility and generalisation.

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Authors' contributions
BM, LM, BG Wrote the main manuscript. BM, LM prepared all the figures. All authors reviewed the manuscript.

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Data availability
Data is available on figshare: https://figshare.com/s/5d3d1005e80f2fbc9fb0 and provided within the manuscript.

Declarations

Ethics approval and consent to participate
This study was conducted in full compliance with the Declaration of Helsinki (https://www.wma.net/policies-post/wma-declaration-of-helsinki/) [72]. Ethical clearance and approval were obtained from the Sefako Makgatho University Research and Ethics Committee (SMUREC), application SMUREC/P/168/2023: PG and the University of Pretoria Faculty of Health Sciences Research Ethics Committee, application 11/2023. The study made use of patients' records and anonymization was applied throughout the data collection period. No communication was done with the patients; hence, patient consent was not required. In this case, we used the hospital approval process governed by Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa [73].

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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