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Examining the association of alcohol use and psychotropic medication adherence among women with severe mental illness in South Africa

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ABSTRACT

Women with severe mental illness (SMI) in South Africa face numerous psychosocial challenges and alcohol use is widely used in this population as a coping strategy. Although hazardous alcohol use has a documented negative effect on medication adherence or chronic illness, research has mostly ignored the role of alcohol on psychotropic medication adherence in women with SMI. The primary aim of this study was to explore the association of hazardous alcohol use on psychotropic medication adherence in adult women living with SMI ($N = 119$), attending a psychiatric clinic for treatment in Cape Town. Medication adherence was based on self-report and hazardous alcohol use was measured with the Alcohol Use Disorders Identification Test (AUDIT). Poisson regression analyses (controlling for education, relationship status, and psychiatric hospitalisations) indicated that hazardous alcohol use was significantly associated with a greater likelihood of psychotropic medication non-adherence. Similar findings were observed for HIV medication non-adherence in the HIV-positive subsample. Study findings highlight the role of alcohol use for medication non-adherence in women with SMI and should be addressed in psychiatric care.

1. Introduction

Women living with severe mental illness (SMI) are faced with numerous health related challenges that require appropriate and timely interventions. Understanding the factors that lead to non-adherence of psychotropic and other medication is a vital component of improving their health-related outcomes. Individuals living with SMI, which includes disorders with primary or secondary psychotic features such as schizophrenia, bipolar disorder, or severe depression, have a life expectancy that is 10 years shorter than their counterparts who do not have a mental illness (Walker et al., 2015). Individuals with an SMI also face multiple biopsychosocial challenges (Wainberg et al., 2017), including physical and mental health comorbidities such as higher rates of obesity, cardiovascular disease, tobacco smoking, and problematic substance use (Seeman, 2015) .These comorbidities, alongside other psychosocial stressors such as unemployment and isolation, make psychotropic medication adherence challenging for individuals with SMI (Velligan et al., 2017).

Individuals with SMI who are non-adherent to their psychotropic medications are at risk of illness deterioration and readmission to hospital (Bitter et al., 2015; Velligan et al., 2017), which increases the utilization of resources and services (Jack et al., 2014). In South Africa, these challenges are compounded by resource-limitations for mental health, the high HIV prevalence and high frequency of heavy episodic drinking (Docrat et al., 2019). It is important to understand the risk factors for psychotropic medication non-adherence in these settings in order to improve health outcomes in this vulnerable group.

Hazardous alcohol use has been consistently found to have a negative impact on numerous health related outcomes, which includes suboptimal adherence to medication (Magura et al., 2014). In one study, one in three South Africans reported current alcohol use of any amount, while one in seven individuals reported binge drinking on the days when alcohol was consumed (Vellios and Van Walbeek, 2017). A South African national survey reported that 5% of women consumed alcohol in a hazardous manner, which was defined as drinking 5 or more standard measures of alcohol on a single occasion in the past 30 days (Stats SA,

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2017). There is a higher prevalence of hazardous alcohol use amongst PLWH, this includes women specifically as well as people with SMI. A study conducted in South Africa and Uganda found the prevalence of unhealthy alcohol use to be 32% amongst an HIV positive population group at the time of ART initiation (Magidson et al., 2019). Although alcohol use has consistently been associated with poorer ART adherence in the broader HIV-infected population, less is known about how alcohol use affects psychotropic adherence among people with SMI, and women in particular.

South Africa, which has the largest HIV epidemic in the world, has a greater proportion of women who are infected than men (Zuma et al., 2016), both in the general population and those living with SMI. In general, the HIV prevalence amongst the SMI population is approximately double when compared to the national HIV prevalence in South Africa. (Zuma et al., 2016). There are numerous co-occurring and converging factors that can account for this higher prevalence in individuals with SMI. For example, internalized and external mental health related stigma remains a major challenge that impacts on affected individuals' ability to access care and remain adherent to prescribed psychotropic treatment (Livingston and Boyd, 2010; Vistorte et al., 2018).Despite the high HIV burden in South African women living with SMI, women have been underrepresented in research on SMI and HIV (Feldman et al., 2019; Woodall et al. 2010), highlighting the importance of addressing the needs of this vulnerable group.

In this study, our first goal was to examine whether hazardous alcohol use was associated with psychotropic medication non-adherence among women living with SMI who were attending a psychiatric clinic for treatment in Cape Town, South Africa. Our secondary goal was to examine whether hazardous alcohol use was associated with ART non-adherence in the subsample of women living with HIV and SMI, given the high prevalence of hazardous alcohol use in the general South African population and SMI population group. We hypothesized that hazardous alcohol use would be associated with an increased likelihood of psychotropic and ART medication non-adherence. This is the first exploratory analysis to our knowledge, that examines the role of alcohol use on ART adherence in an SMI sample living in a low or middle income country (LMIC).

2. Methods

2.1. Participants and procedure

We recruited female patients presenting to a peri-urban community psychiatric clinic. The area is predominantly inhabited by Black Africans, has a high HIV prevalence, and high rates of poverty and unemployment (Stats SA, 2012). The community clinic is a government funded institution that provides an array of primary health care services to approximately 1500 patients per month (Kama, 2017). Speciality psychiatric services are provided by two nurses, one of whom has an additional qualification in psychiatric nursing. The mental health clinic sees approximately 200 patients per week who have a confirmed or suspected psychiatric disorder. The patients present with a range of psychiatric diagnoses, though SMI is common given that most patients are referred after being discharged from secondary and tertiary level psychiatric facilities. The nursing staff incorporate basic psychological and social services into their assessment and management plans. A part-time psychologist provides individual psychotherapy and social worker services for referred patients.

Data for the study were collected between February and November 2015. Selection of participants was carried out using convenience sampling. The medical charts of clinic patients who were presenting for routine follow-up visits were screened by a trained psychiatric nurse to determine whether the patient met study inclusion criteria. Any patient whose mental status was acutely impaired due to active psychotic symptoms or marked cognitive impairment, was not referred to the study research assistant.

Study inclusion criteria were the following: (1) female patients attending the community psychiatric clinic; (2) between 18 and 60 years old; (3) had a clinical diagnosis of SMI as documented in the patient's clinic file and (4) prescribed psychotropic medication requiring daily dosing. The following diagnoses were included in the study's definition of SMI: schizophrenia, schizoaffective disorder, bipolar disorder, or major depressive disorder with psychotic features. Patients were excluded from study participation if they met any of the following criteria: (1) were actively psychotic, (2) unable to provide informed consent, or (3) had a primary diagnosis of dementia or intellectual disability. Patient diagnoses at the clinic are given by a psychiatry resident who provides direct clinical care to the patient. Patients attending the psychiatric clinic are reviewed at a minimum of every 6 months by a psychiatric resident. The resident is responsible for diagnostic review, which includes assessing the severity of the psychiatric disorder and treatment optimisation. For patients who are referred to the clinic from an outside psychiatric facility, the patient's diagnosis is confirmed by a specialist psychiatrist from the outside facility and is corroborated by the treating team at the Community Clinic via an additional clinical assessment.

Potential participants who met initial eligibility criteria ($N = 140$) were then referred to the study research assistant. The research assistant explained the study goal to potentially eligible participants and asked about their interest in participating. All referred participants completed the informed consent process. Five participants were on injectable psychotropic drugs and one participant was not prescribed psychotropic medication so we could not assess psychotropic medication adherence. These six participants were thus initially enrolled but were not eligible for inclusion in analyses. Further, we were unable to verify the SMI diagnosis of 15 individuals due to incomplete or contradictory medical chart information. Thus, the final sample was comprised of 119 participants. All study procedures (both written and verbal) were conducted in isiXhosa, the local language. Study ethics approval was granted by the University of Cape Town's Faculty of Health Sciences Human Research Ethics Committee and institutional approval was granted by the facility manager at Gugulethu community psychiatric clinic.

2.2. Measures

Demographic and clinical characteristics. Age, education, income, employment, relationship status, HIV status, and number of previous psychiatric hospitalizations were assessed via a questionnaire that we developed and administered to all participants. Participant self-reported HIV status was corroborated by examining participant medical charts for HIV status diagnosis.

Hazardous alcohol use. The Alcohol Use Disorders Identification Test (AUDIT) was used to assess hazardous alcohol use. The AUDIT is a 10-item self-report measure, with items scored on a 0 – 4 scale. Higher values represent greater alcohol consumption or more problems associated with alcohol use. We used a cut-off score of 8 or above to indicate hazardous alcohol use, consistent with previous research (Conigrave et al., 1995). The AUDIT was administered in IsiXhosa, the indigenous language that was spoken by all the participants. The results were then translated and captured in English.

Psychotropic medication adherence. A 4-item self-report assessment of psychotropic medication adherence was adapted from a measure originally developed to assess adherence to blood pressure medication (Morisky et al., 1986). The wording of the current questions was adapted to focus on the participant's psychotropic medication. Questions asked different variations of whether the participant stopped taking their medications in the past four weeks, including "Do you ever forget to take your medications?" and "When you feel better, do you sometimes stop taking your medications?". All questions were answered as yes/no. Participants who answered 'yes' to at least one item were considered nonadherent.

HIV medication adherence. We used a one-item measure used in

prior research to assess level of antiretroviral therapy (ART) adherence for participants who were HIV-positive (Edward L. Machtinger and Bangsberg, 2005). The item asks participants to report on their percentage of ART adherence over the last month, using a 5-point likert scale. Zero prercent indicates that none of the tablets were taken,50% indicates that half of the tablets that were prescribed were taken by the participant. Participants who reported 100% adherence were classified as adherent; anything less than 100% was classified as nonadherent. Early ART adherence studies had suggested 95% or greater ART adherence as being the ideal for optimal health related outcomes such as a reduction in the occurrence of opportunistic infections (Paterson et al., 2000).A more recent meta-analysis has suggested that a lower cut off may be warranted as the 95% adherence requirement may serve as a barrier for initiation of therapy in the early stages of HIV infection (Bezabhe et al., 2016).We utilised the higher threshold as a cut off for adherence for the purposes of our study. Previous research has shown the viability of using self-report as a measure of ART adherence (Simoni et al., 2006).

2.3. Data analytic plan

The initial data collected was captured and double checked by the Principal investigator. The results were then reviewed by the Supervisor and Statistician. Descriptive statistics were first examined for the entire sample and then stratified by psychotropic medication adherence classification (adherent vs nonadherent). The primary analysis examined the effect of hazardous alcohol use on dichotomous psychotropic medication adherence in patients with SMI. The secondary analysis examined the effect of hazardous alcohol use on dichotomous ART adherence. Demographic and clinical variables that were significantly different between the two adherence groups were included in the final models, in addition to any clinical covariates that were deemed theoretically important. Poisson regression analyses with robust error variance and no offset was used to estimate relative risk ratios (RRs), adjusted risk ratios (aRRs), and 95% confidence intervals (CIs). SAS version 9.4 (SAS Institute, Cary, NC, USA) was used for all analyses.

We also calculated a post-hoc power estimate to detect a statistically significant association between hazardous drinking and non-adherence, given the sample size of 119, 46 of whom were adherent to psychotropic medications. For a medium-sized difference in psychotropic adherence rates (d= .5), using a one-tailed independent sample t-test, and assuming .05 significant level, we calculated this study would have a power estimate of 0.905, using the pwr.chisq.test function within the R pwr package (Champely, 2020). We also conducted a post-hoc power analysis for our exploratory analysis, the effect of hazardous drinking on ART medication adherence using the R package called Exact (Calhoun, 2020). The power to detect a significant difference in ART adherence between hazardous alcohol users and non-hazardous alcohol users was 0.31, indicating an analysis with low power. The limitations of this are described in the Discussion section.

3. Results

Table 1 provides demographic and clinical characteristics for the total sample stratified by psychotropic medication adherence classification (adherent vs nonadherent). Participants who were non-adherent to their psychotropic medication most commonly reported forgetting to take their medications (endorsed by 84%). The other three reasons for non-adherence (was careless, stops taking medications when feels better, medications make them feel worse) were endorsed to a lower extent (21-22%). Participants who were non-adherent to their psychotropic medication were less educated, more likely to be in a committed relationship, and according to the AUDIT, had higher average total scores and more likely to drink hazardously.

Table 2 depicts the regression analyses predicting psychotropic medication non-adherence. Education and relationship status were included as covariates, as well as psychiatric admission history to control for the severity and chronicity of illness. Hazardous alcohol use was associated with a greater likelihood of psychotropic medication non-adherence in both the unadjusted analysis, RR = 1.63 (95% CI [1.30, 2.03]), and the adjusted analysis, aRR = 1.33 (95% CI [1.03, 1.72]). Being in a committed relationship was also associated with an increased likelihood of psychotropic medication non-adherence in the adjusted model, aRR = .1.53 (95% CI [1.15, 2.03]), whereas having more education was associated with a decreased likelihood of psychotropic medication non-adherence, aRR = .56 (95% CI [.32, .98]).

We conducted a similar analysis for ART non-adherence with the HIV-positive subsample ($N = 45$) using the same covariates as the psychotropic medication model, given the high correlation between psychotropic non-adherence and ART non-adherence (polychoric $r = .78$, $p < .001$). In the unadjusted ART non-adherence model, hazardous alcohol use was related to an increased risk of ART non-adherence, RR = 1.75 (95% CI [1.06, 2.90]). In the model adjusted for education, relationship status, and previous psychiatric hospitalizations, hazardous alcohol use was no longer significant, aRR = 1.32 (95% CI [.76, 2.29]). None of the other covariates were significant in the adjusted model. Results from both analyses are presented in Table 2.

Table 1
Demographic and clinical characteristics stratified by psychotropic medication adherence status.

Variable	Entire sample($N = 119$)% (n)	Adherent ($n = 46$)% (n)	Nonadherent ($n = 73$)% (n)	Test statistic F or X^2
Age, *M (SD)*	44.13 (9.25)	44.85 (9.94)	43.67 (8.83)	.45
Education (≥ grade 12)	19.3 (23)	32.6 (15)	11.0 (8)	8.48**
Employed (part-time/ full-time)	12.6 (15)	17.4 (8)	9.6 (7)	1.56
Income (> R2000/ month)	42.0 (50)	47.8 (22)	38.4 (28)	1.04
HIV positiveˆ	41.7 (45)	36.6 (15)	44.8 (30)	.70
In a committed relationship (married, cohabitating, or dating)	46.2 (55)	28.3 (13)	57.5 (42)	9.73**
SMI diagnosis				1.02
Schizophrenia/ schizoaffective disorder	31.9 (38)	37.0 (17)	28.8 (21)	
Bipolar disorder	19.3 (23)	19.6 (9)	19.2 (14)	
Major depression	48.7 (58)	43.5 (20)	52.1 (38)	
Previous psychiatric hospitalizations (≥ 1)	61.3 (73)	69.6 (32)	56.2 (41)	2.14
AUDIT total score, *M (SD)*	2.73 (6.51)	.70 (1.85)	4.01 (7.94)	7.75**
Hazardous alcohol use (AUDIT ≥ 8)	11.8 (14)	2.2 (1)	17.8 (13)	6.64**

Note. *$p < .05$. **$p < .01$. ***$p < .001$. ˆ$n = 11$ were unaware of their HIV status so there were a total of $N = 108$ for this analysis; $n = 41$ knew their status in the adherent group and $n = 67$ knew their status in the non-adherent group.

4. Discussion

In this under-researched area, we report on findings from a sample of women living with SMI in peri-urban Cape Town. Our findings support our hypothesis that hazardous alcohol use is associated with increased risk of psychotropic medication non-adherence. We observed similar effect sizes for the role of alcohol use in ART non-adherence for the subsample of HIV-positive women, despite the estimates not being significant in the adjusted analyses. We also consistently found that being in a committed relationship and less education were both negatively associated with medication adherence.

Table 2
Poisson regression analyses predicting nonadherence to psychotropic medication and ART.

	Psychotropic medication nonadherence ($N = 119$)				ART nonadherence ($N = 45$)			
Characteristics	RR	95% CI	aRR	95% CI	RR	95% CI	aRR	95% CI
Hazardous alcohol use	1.63	[1.30, 2.03]	1.33	[1.03, 1.72]	1.75	[1.06, 2.90]	1.32	[.76, 2.29]
Education (≥ matric)	.51	[.29, .91]	.56	[.32, .98]	.44	[.13, 1.51]	.46	[.14, 1.50]
Committed relationship	1.58	[1.18, 2.11]	1.53	[1.15, 2.03]	1.83	[.94, 3.56]	1.77	[.94, 3.31]
Previous psychiatric hospitalizations (≥ 1)	.81	[.61, 1.07]	.78	[.60, 1.01]	1.24	[.69, 2.26]	1.02	[.57, 1.81]

Note. RR = relative risk. aRR = adjusted relative risk. The aRR model includes all four predictors.

The fact that hazardous alcohol use was associated with psychotropic medication non-adherence is consistent with our study hypotheses and prior literature. A systematic review on adherence to psychotropic treatment amongst individuals living with schizophrenia or bipolar disorder found that alcohol use was a robust predictor of poor psychotropic medication adherence (García et al., 2016). However, less is known about hazardous alcohol use and psychotropic medication adherence in LMIC settings, where binge-drinking is common, together with several other psychosocial stressors that are associated with poor mental health outcomes (Mayston et al., 2012). Our study also found similar results for the role of hazardous alcohol use in the subsample living with HIV. This finding dovetails prior research demonstrating the negative effects of alcohol use on ART adherence. A recent systematic review and meta-analysis showed that individuals who consume alcohol have twice the odds of ART non-adherence compared to those who do not use alcohol (Velloza et al., 2020). Given the challenge of retaining patients with comorbid SMI and HIV in ART care in South Africa (Joska et al., 2014), this finding is especially relevant.

These findings highlight the importance of regularly screening and treating hazardous alcohol use in women living with an SMI, as it may affect adherence to psychotropics and ART. Alcohol use may be overlooked as a factor affecting women's adherence, given women's lower rates of alcohol use, as compared to men (Shield et al., 2020). Social desirability may be an additional factor related to underreporting of extent of alcohol use amongst men and women in Sub-Saharan Africa (Magidson et al., 2019).

In the context of comorbid HIV infection and mental illness, several factors may contribute to medication non-adherence. These include biological effects of HIV on the brain (i.e. HIV-associated neurocognitive disorders), HIV-associated stigma, and the additional stigma associated with living with a mental illness. HIV-associated neurocognitive disorders are estimated to occur in 53% of PLWH in South Africa (Mogambery et al.2017) and are a known driver of impaired activities of daily living, including antiretroviral treatment (ART) non-adherence (Heaton et al., 2004). HIV-associated stigma remains a barrier to accessing care and ART adherence ((Katz et al., 2013). People living with HIV (PLWH) who are also living with a mental disorder face a double burden of stigma, which may limit access to both ART and psychotropic medications (Sorsdahl et al., 2010). Living with both a diagnosis of HIV and SMI and the treatment implications thereof, results in a greater pill burden for the individual. An increased pill burden is associated with medication non-adherence in PLWH (Paramesha & Chacko, 2019). Data suggest that women living in impoverished settings carry the heaviest load both in the home and work environment, as opposed to their male counterparts (Messias et al., 1996).This would impact negatively on the ability of women living in such settings to adhere to their treatment regimens.

We also found that having lower education levels was related to psychotropic medication non-adherence, consistent with prior research (Semahegn et al., 2020). Those with less education are also more likely to be unemployed, potentially making it difficult to maintain adherence due to food insecurity, especially in LMIC (Moomba and Van Wyk, 2019). An Ethiopian study found that a common reason for non-adherence to psychotropic treatment for individuals with schizophrenia was inadequate availability of food to counteract medication side effects of appetite increase and the perceived high potency of antipsychotic medications (Teferra et al., 2013). Given South Africa's high levels of income inequality (Burns et al., 2017), we would expect that this would also be an important consideration when assessing reasons why patients become non-adherent to their treatment. This is an area that could be explored in further studies.

An unexpected finding was that women who were non-adherent to their psychotropic medication were more likely to be in a committed relationship (either cohabitating or married), as compared to women who were adherent. Although we did not have specific hypotheses around this variable (it was included as a demographic covariate), the consistent large effect size of the variable is worth exploring and understanding more. A large body of research generally supports that being married or in a committed relationship is a protective factor for health-related outcomes, including cancer (Buja et al., 2018), cardiovascular disease (Otto, 2018) and hypertension (Ramezankhani et al., 2019). A study in Egypt showed that men and women who had a diagnosis of bipolar I disorder and who were married had higher levels of psychotropic medication adherence, in comparison to their non-married counterparts (Okasha et al., 2020). Similarly, an Ethiopian study showed participants with good social support had better adherence to psychotropic medication (Stentzel et al., 2018). The divergent findings in the current study may be explained by the fact that women in committed relationships have more domestic responsibilities related to their partner and children, which may serve as barriers for picking up medication or taking it on time . Educating partners and possibly incorporating them into the treatment plan may help support women's improved adherence. Global research on promotion of behaviours to reduce HIV risk and improve adherence to ART, supports including partners in treatment (Crepaz et al.,2015).

The current study has several limitations which must be considered. Firstly, a cross sectional study methodology was used, we are thus unable to illustrate whether a temporal relationship exists between hazardous alcohol use and SMI symptomatology or the directionality of this association. Cohort and intervention studies would more clearly elucidate this. The aim of our study was to obtain a real world understanding of the association between alcohol use and psychotropic medication adherence among women with severe mental illness, in this context, a cross-sectional study was appropriate. Future studies should also include a question about age at onset of alcohol use and age of diagnosis of severe mental illness. Secondly, we used a convenience sampling method and only examined adherence of women who were attending a psychiatric clinic. It is possible that women who were non-adherent were less likely to attend their clinic appointments altogether. Future studies should focus on locating the clinic non-attendees by conducting home visits, to ascertain the factors that result in their non-adherence. Secondly, we relied on self-reported measures for our primary constructs of interest, alcohol use and medication adherence, rather than objective measures. Future studies should thus utilise both objective measures such as pill counting, where possible.

In the absence of a validated self-report psychotropic medication adherence measure in South Africa, the Morisky scale was an appropriate tool to modify. The assessment tool used for psychotropic medication adherence assessed overall adherence to all prescribed psychotropics. This is a potential limitation as some patients may show differential adherence to specific psychotropic medications. Future

studies should explore adherence to specific psychotropic medications potentially with both self-report as well as biomarkers.

Our study was conducted with participants from one clinic only, multicentre studies should be considered in the future. Furthermore, our exclusion of actively psychotic patients may have also introduced selection bias into the study, as participants needed to have fairly controlled psychiatric symptoms to be eligible for participation. Furthermore, standardised assessments were not used to determine the psychiatric diagnosis.

Another limitation is the exploration of only alcohol as a substance under consideration within our study. Future studies should focus on a broader list of substances such as cannabis, methamphetamine, heroin and methaqualone and their impact on adherence in a similar population. Finally, although our HIV subsample was small and likely underpowered to detect effects, the similarity of RR point estimates for alcohol, education, and relationship status between the psychotropic and ART models bolsters the findings. Future research should recruit a larger group of individuals who are living with SMI and HIV to increase the power to detect significant effects. South Africa is a country with a unique cultural, social and political environment. This may limit generalisability of our findings. Conversely, it is also one of the study's strengths, as it adds to the much-needed literature on SMI in this resource constrained context.

Despite these limitations, the study provides novel findings regarding the role of hazardous alcohol use in psychotropic medication non-adherence in women living with SMI in South Africa. A further novelty of our study is that it was conducted amongst a real-world sample of SMI women, with and without HIV, in order to report on prevalence and correlates of comorbidity. It is thus a practical contribution that could be useful for other clinicians who are working in similar resource limited settings. Study findings highlight the importance of addressing the potential role of alcohol use in this population and making it a focus of clinical attention. A truly patient-centred service could integrate alcohol use treatment services into general care and ensure that available services were tailored to women with SMI. Future areas of research include an in-depth exploration of the role of relationship status on adherence to psychotropic and other medication, especially in women. Given the high levels of intimate partner violence (IPV) in South Africa, future studies should specifically enquire about its absence or presence and the possible link to non or poor adherence to medication. For example, we know there are still significant levels of HIV status non-disclosure amongst South African women and this non-disclosure has direct implications on ARV adherence as these medications would need to be concealed in the context of non-disclosure. This also may apply to non-disclosure of SMI status.

Overall, it remains important for all healthcare professionals who manage women with SMI to regularly test this vulnerable group for HIV and to also screen them for hazardous alcohol use as these factors have an impact on psychotropic adherence. Although our study focused on women only, it is essential that all individuals living with a SMI are screened for hazardous use of alcohol and other addictive substances.

Author statement

All authors listed on this manuscript have made a significant contribution to the work. All authors have read the manuscript, attest to the validity and legitimacy of the data and its interpretation, and agree to its submission. All authors confirm that the manuscript is the authors' original work, has not received prior publication, and is not under consideration for publication elsewhere.

Ethical statement

We confirm that any aspect of the work covered in this manuscript, that involves human patients has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript. Informed consent was also obtained from all participants.

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Declaration of Competing Interest

All authors confirm that they have no conflicts of interest to declare.

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