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Maternal substance and alcohol use and contextual issues

Edited by
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Maternal substance and alcohol use and contextual issues

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Editorial: Maternal substance and alcohol use and contextual issues

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Editorial on the Research Topic
Maternal substance and alcohol use and contextual issues

Recent research advancements have delineated the impact of perinatal substance and alcohol use on the health of mothers and fetuses/infants (1–3) and also the bidirectional impact between perinatal substance and alcohol use and contextual issues (4–10). Adverse effects of perinatal substance and alcohol use include miscarriage, intrauterine growth restriction, low birth weight, shorter gestational weeks, increases in NICU admission, and stillbirth (1, 11–15). Recent evidence also identified independent adverse effects of breastfeeding while using alcohol on infant neurocognitive and physical development (16). This is concerning given the fact that even among people who stop drinking during pregnancy, many will return to drinking post-partum. A paucity of evidence about drinking during breastfeeding and few recommendations contribute to this phenomenon (17).

When perinatal substance and alcohol use occurs, there are often co-occurring psychosocially and culturally relevant contextual issues, such as socioeconomic disadvantage, lack of social support, trauma exposure, and depression (18–20). Given the significant involvement of perinatal substance and alcohol use in compromised sexual health (7, 21), these intertwined physical and mental health issues are clustered as a SAVA syndemic (substance abuse, violence, and AIDS) (22).

While using a single substance or alcohol during perinatal periods leads to pregnancy, birth, and infant complications (1, 2, 23–27), combined use of substances and alcohol use could further exacerbate their adverse effects on maternal-infant health (18–20, 28, 29). Because of continued cannabis legalization (30), an increase in perinatal cannabis use is a concern (31) (25, 26). The consequences of legalizing cannabis need to be delineated for pregnant and breastfeeding people (32–35).

The opioid epidemic in the United States (US) has led to a significant increase in perinatal opioid use (36). On top of this, the prevalence of overall perinatal substance and

alcohol use as well as relevant contextual issues including violence exposure and maternal depression and anxiety has worsened since the global COVID-19 pandemic (37–42).

The current Research Topic, Maternal Substance and Alcohol Use and Contextual Issues, therefore focused on a set of qualitative and quantitative studies on maternal substance and alcohol use and associated contextual issues, with the goal of proposing new approaches to provide evidence-based information and treatment interventions. This Research Topic demonstrates a diversity in study settings, types of studies, and topic focus. The settings include Poland, South Africa, and the Philippines, in addition to the United States. The studies included both qualitative and quantitative research, and ranged from pilot and usability testing studies, to systematic reviews, to survey research. The topics included prenatal substance and alcohol use, stigma and mental health issues among pregnant and parenting people, and postpartum smoking relapse and substance use.

Two qualitative studies from South Africa (Petersen Williams et al., Petersen Williams et al.) investigated the development of interventions to encourage alcohol abstinence during pregnancy and breastfeeding. In both studies, the need for an alcohol intervention program was highlighted and informed the adaptation process for interventions that are culturally relevant and acceptable to the needs of the local context. Another study (Nguyen et al.) examined knowledge, attitudes, practices, and beliefs regarding prenatal alcohol consumption. Of particular interest in this study conducted in the Philippines (Huang et al.) was the widespread consumption (75%) of a local alcoholic beverage during pregnancy, which was believed to not contain alcohol and, in some instances, even fed to infants. Encouragingly, nearly all mothers (98%) were willing to reduce consumption when told that the practice negatively impacts pregnancies. An intervention study in Poland (Okulicz-Kozaryn et al.) aimed to reduce the risk of prenatal alcohol exposure in the general population of women of childbearing age including reduction of risky alcohol consumption, increasing effective contraception use, and increasing use of professional support to address the complex psychological, medical and social challenges which may increase risk of alcohol use during pregnancy. Follow-up data indicated that risky alcohol consumption dropped by 81%; contraception use increased by 15% and visiting a gynecologist increased by 39%. The most prominent changes were observed in the moderate-risk group.

Opioid use disorder is a leading cause of pregnancy-associated deaths. One study in the United States (Nguyen et al.) found that among patients who were incarcerated and initiated buprenorphine (BUP) treatment, the majority (97%) remained on BUP at delivery compared to those who were not incarcerated at BUP initiation (79%). Pregnant and parenting women recovering from substance use disorder (SUD) are at risk of insufficient recovery support. Another US study (Isaacs et al.) tested the usability and acceptability of a Plan of Safe Care (POSC) platform which combined a mobile health app with a web-based case management system. Family services staff, treatment center staff, and mothers with SUD rated the platform as usable and acceptable. A qualitative study (Young-Wolff et al.) in the US found that coping with mental health symptoms and stress were identified as drivers of perceived COVID-19 pandemic-related increases in prenatal cannabis use in 2021.

Researchers in the US evaluated the delivery of attentional retraining (AR) for smoking cues in perinatal smokers, also utilizing a mobile intervention (Forray et al.). They found evidence that AR reduced attentional bias compared with controls but found no evidence that AR reduced craving or smoking during the study period.

Some of the contextual issues to do with maternal substance use were also addressed in the Research Topic. In a systematic review and meta-analysis (Pacho et al.), the authors provided evidence of an increased risk of postpartum depression among pregnant substance users, and this was particularly the case for those using multiple substances or tobacco.

Stigma remains a huge barrier to receiving care for SUD, particularly among pregnant and parenting people. Another US study (Lipsett et al.) explored stigma reduction practices within the research community that can increase the uptake of evidence-based treatment programs and proposed six strategies for this to happen.

The collection of these publications gives us a glimpse of what is known about maternal substance and alcohol use and relevant contextual issues and what are the future research directions that subsequent studies need to follow.

Author contributions

YW: Conceptualization, Writing – original draft, Writing – review & editing. PP: Conceptualization, Writing – review & editing. KI: Writing – review & editing.

Conflict of interest

Author KI was employed by the company SciConsult Solutions.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Incarceration status at buprenorphine initiation and OUD treatment outcomes during pregnancy

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Introduction: Opioid use disorder (OUD) is a leading cause of pregnancy-associated deaths. OUD treatment with buprenorphine (BUP) reduces overdose risk and improves perinatal outcomes. Incarceration can be a barrier to receipt of OUD treatment during pregnancy and postpartum. The objective of this study was to examine differences in BUP continuation at delivery by patients' incarceration status at the time of BUP initiation.

Methods: This is a secondary analysis of a retrospective cohort study of pregnant patients with OUD who delivered at an academic medical center and initiated BUP between January 1, 2018, and March 30, 2020. The primary outcome was BUP continuation at delivery, abstracted from the state prescription monitoring program and electronic medical record, along with incarceration status. Bivariate analysis was used to assess the relationship between BUP continuation and incarceration status.

Results: Our sample included 76 patients, with 62% of patients incarcerated at BUP initiation (n = 47). Among the entire sample, 90.7% (n = 68) received BUP at delivery. Among patients who were incarcerated at BUP initiation, 97% remained on BUP at delivery; among patients who were not incarcerated at BUP initiation, 79% remained on BUP at delivery (p = 0.02).

Conclusion: In our sample from a health system housing a care model for pregnant and parenting people with OUD with local jail outreach, BUP continuation rates at delivery were high, both for patients who were and were not incarcerated at BUP initiation. Findings are intended to inform future work to develop and evaluate evidence-based, patient-centered interventions to expand OUD treatment access for incarcerated communities.

KEYWORDS

opioid use disorder (OUD), perinatal, incarceration, buprenorphine, maternal health

1. Introduction

In the United States, opioid use disorder (OUD) is a leading cause of pregnancy-associated deaths (1). Medications for OUD (MOUD), including buprenorphine (BUP), reduce overdose risk and improve perinatal outcomes (2). One important factor influencing OUD treatment continuation is the involvement of the criminal legal system (3). SAMHSA recommends MOUD be offered to all people with OUD during incarceration (4). However, several barriers to MOUD provision during incarceration and its transitions pre/post-release exist, such as inconsistencies across states in insurance coverage (e.g., Medicaid not accessible during incarceration) and levels of access to medical specialty services across institutions (e.g., carceral systems are fiscally responsible for medical care) (5, 6).

Receipt of medications for OUD during incarceration is rare, including during pregnancy and postpartum; Sufrin et al. (7) recently reported that nearly one third of pregnant people with OUD entering to prisons and jails were either withdrawn from treatment or not offered MOUD while withdrawing from opioids. This is unfortunate, as provision of MOUD during incarceration can promote positive social outcomes, such as decreased recidivism (8), decreased mortality post-release (9), and better community engagement (10). Other than high rates of MOUD discontinuation occurring postpartum in jails and prisons, little is known regarding OUD treatment outcomes among incarcerated pregnant individuals.

Nonetheless, innovative models of care are emerging to address these significant unmet treatment needs among people who are incarcerated, including during the highly vulnerable life-course periods of pregnancy and postpartum. For example, a recent study done in North Carolina highlighted the potential of a prison-academic partnership to bolster MOUD continuity for pregnant and postpartum people with OUD (11). Likewise, our institution houses an integrated OBGYN-Addiction program consisting of nurses and medical providers with expertise in both OBGYN and Addiction Medicine as well as support staff, behavioral health clinicians and subspecialty consultants who provide robust, recovery-oriented wrap-around services (12). An integral component of this program includes its partnerships with local jails where pregnant individuals with OUD are referred to our health system for evaluation and initiation of OUD treatment. Specifically, pregnant people who present with opioid withdrawal at incarceration are transported to our OBGYN antepartum service for evaluation and are offered BUP initiation while inpatient; before discharge, outpatient follow-up is coordinated by nursing staff with the local jail and the OBGYN-Addiction program.

This partnership offers an opportunity to evaluate OUD treatment outcomes among this vulnerable, highly understudied population. The primary objective of this study is to compare BUP continuation rates until delivery by incarceration status at BUP initiation among a cohort of pregnant patients with OUD seen within our health system. In doing so, we discuss our findings in the context of the clinical practices that our innovative integrated OBGYN-Addiction care model for pregnant and parenting people utilizes to expand its reach to local incarcerated individuals with OUD.

2. Methods

2.1. Design

The current study is a secondary analysis of a retrospective cohort study exploring health and addiction outcomes for pregnant and postpartum patients who received buprenorphine for OUD at Virginia Commonwealth University (VCU), an academic medical center. Briefly, electronic medical record of patients receiving BUP (sublingual tabs or films, buprenorphine or buprenorphine-naloxone) at any point during pregnancy and/or through 1 year postpartum from January 2017 to March 2020 were included. Detailed methods for the parent study are described elsewhere (13). This academic medical center has a designated OBGYN-Addiction clinic staffed by Obstetricians that provides integrated care, behavioral and medical care for many of the individuals in this study. While receiving care at this clinic was not a requirement of study participation, many individuals did receive care in this clinic. A study team performed a manual abstraction of the electronic medical record, which included review of buprenorphine prescriptions documented by the Virginia Prescription Monitoring Program. Chart abstractions were done in 4-week increments during the perinatal period for clinical and psychosocial data, including pregnancy outcomes, incarceration status and OUD treatment outcomes. Incarceration status was ascertained from provider documentation. Chart abstractions started at the time of initial BUP receipt during pregnancy and continued until delivery. The larger study was done with IRB approval from Virginia Commonwealth University.

2.2. Participants

Patients were included in the current secondary analysis if pregnant at the time of BUP initiation, had at least 8 weeks of longitudinal data (with complete outcome ascertainment), delivered at VCU, and started BUP while inpatient at the study institution. See **Figure 1** for more details.

2.3. Analytic plan

To evaluate differences in demographic and clinical variables of patients who were incarcerated at BUP initiation versus patients who were not incarcerated, we used chi-square tests and student *t*-tests. Next, we again used chi-squared and *t*-tests to examine the relationship between our primary outcome, BUP continuation at delivery, and our main exposure variable of interest, incarceration status at BUP initiation, within our final sample. All analysis was done with STATA 17 (14).

3. Results

Our study included 75 individuals (**Table 1**). Most of our sample (62.6%) was incarcerated at BUP initiation, enrolled in Medicaid (69.3%), identified as white (73.3%), and 30.7% had

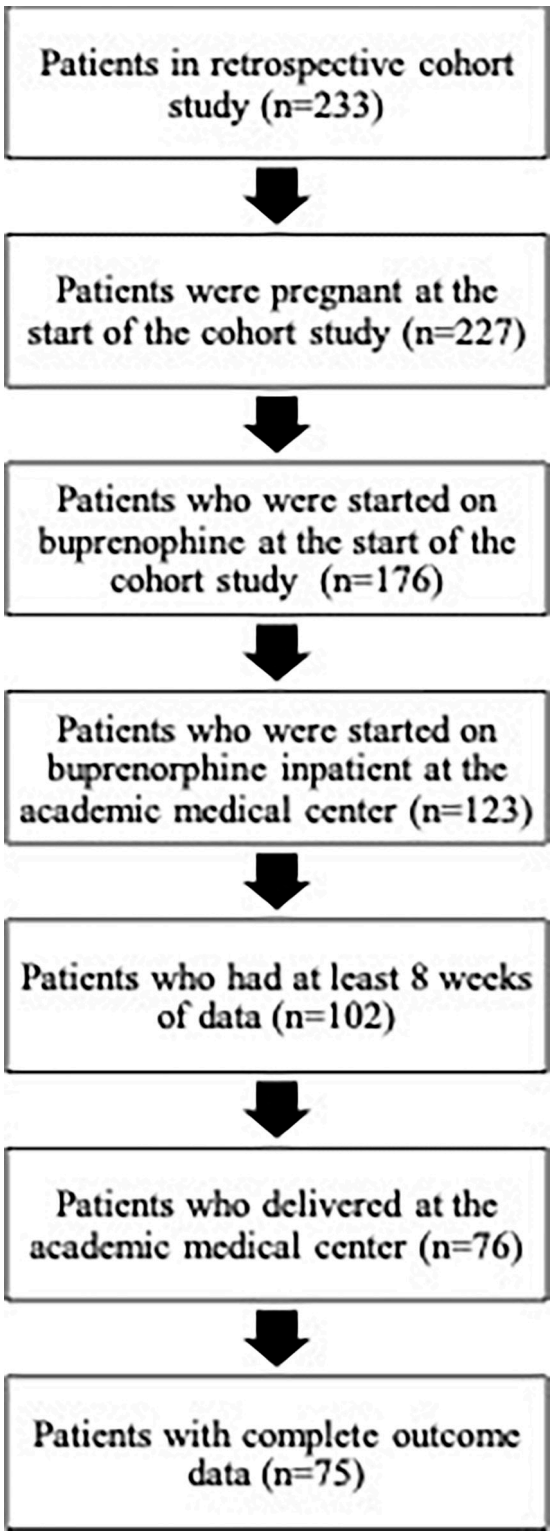

FIGURE 1
Flowchart of obtaining study sample from the parent retrospective cohort study through exclusion criteria.

a high school diploma or GED. The median dosage of BUP after inpatient BUP induction was 12 mg daily (range 2, 24). Individuals who started BUP while incarcerated were less likely to have current Medicaid coverage than their non-incarcerated counterparts (61.7% vs. 82.1%; p-value = 0.045), as documented at the time of buprenorphine initiation.

Regarding BUP continuation during pregnancy, most individuals (90.7%; n = 68) in our sample remained on BUP at delivery. The proportion continuing BUP until delivery was slightly higher among individuals who were incarcerated at time of BUP initiation compared to individuals who were not incarcerated (95.7% vs. 82.1%; p-value = 0.05).

4. Discussion

Within our sample, results demonstrate similarly high BUP continuation rates at delivery regardless of incarceration status at BUP initiation during pregnancy. These findings are encouraging, as incarceration is typically a barrier to OUD treatment. At our institution, we developed a partnership with local jails where pregnant individuals who present with opioid withdrawal at incarceration are referred to our hospital antepartum service for evaluation and initiation of BUP with outpatient follow-up after discharge. We postulate that this OBGYN-Addiction care model may have contributed to our positive findings.

Incarceration-based MOUD programs can positively impact health outcomes. A recent study interviewed jail representatives across the United States to evaluate available resources and practices. Authors report that 96% of jails have a physician-approved protocol to address opioid withdrawal; however, fewer (81%) use an FDA-approved medication for withdrawal management (15). A study in England found MOUD provision in prisons was associated with a 75% reduction in all-cause mortality and an 85% reduction in fatal drug-related poisoning in participants' first months post-release (9). Similarly, in Rhode Island, no study participants who started BUP while incarcerated experienced an overdose after release nor reported any opioid use recurrence 6 months post-release (16). Our study results extend the findings of these studies into the perinatal period, overall demonstrating the important role that incarceration based MOUD programs could play in reducing morbidity and mortality due to OUD throughout transitions in and out of incarceration.

Common models of MOUD provision for incarcerated people include: jail/prison staff transporting patients to clinic, jail/prison staff themselves picking up medications to bring back to patients, and integrated clinics within jails/prisons (17). The program embedded within the health system from which this study derives provides outpatient substance use disorder treatment integrated with OBGYN care. As part of this program, providers travel to one local jail to provide care on site, and other jails transport pregnant patients on BUP to the health system outpatient OBGYN clinic approximately monthly for OUD treatment follow-up while incarcerated during pregnancy (12). Recently, due to the COVID-19 pandemic, some jails and prisons have implemented telemedicine to provide further flexibility for MOUD (18). While we found high rates of BUP continuation at delivery for incarcerated patients, it is important that this finding not be interpreted as a recommendation for incarceration as an addiction treatment modality. Carceral systems are fiscally responsible for the healthcare of all inmates and thus may coincidentally serve

TABLE 1 Demographic and clinical variables of patients in study sample, by incarceration status at buprenorphine (BUP) initiation**.

	Total (n = 75)	Not incarcerated at BUP* initiation (n = 28)	Incarcerated at BUP initiation (n = 47)	p-value
Age (mean; std)	28.9 ± 4.4	28.5 ± 3.5	29.2 ± 4.9	0.47
Education				0.299
Less than high school diploma	10 (13.3)	7 (25.0)	3 (6.4)	
High school diploma/GED	23 (30.7)	11 (39.3)	12 (25.5)	
College education	9 (12.0)	3 (10.7)	6 (12.8)	
Not reported	33 (44.0)	7 (25.0)	26 (55.3)	
Race[†]				0.001
Black or African American	19 (25.3)	13 (46.4)	6 (12.8)	
White	55 (73.3)	15 (53.6)	40 (85.1)	
Not reported	1 (1.3)	0 (0.0)	1 (2.1)	
Insurance[‡]				0.045
Medicaid	52 (69.3)	23 (82.1)	29 (61.7)	
Private	3 (4.0)	2 (7.1)	1 (2.1)	
None	12 (16.0)	1 (3.6)	11 (23.4)	
Other	8 (10.6)	2 (7.1)	6 (12.8)	
Comorbid mental health conditions[§]				0.591
No	27 (36.0)	9 (32.1)	18 (38.3)	
Yes	48 (64.0)	19 (67.9)	29 (61.7)	
Family history of substance use disorder				0.991
No	27 (36.0)	13 (46.4)	14 (29.8)	
Yes	25 (33.3)	12 (42.9)	13 (27.7)	
Not reported	23 (30.7)	3 (10.7)	20 (42.6)	
Co-occurring substance use disorder[‖]				0.050
No	43 (57.3)	12 (42.9)	31 (66.0)	
Yes	32 (42.7)	16 (57.1)	16 (34.0)	
Estimated gestational age at delivery (median; range) [¶]	39 (23, 41)	38 (23, 41)	39 (30, 41)	0.857
Dose of BUP at discharge from inpatient BUP initiation (median; range) [¶]	12 (1, 24)	12 (2, 24)	10 (2, 24)	0.691
Incarcerated at delivery				<0.001
No	45 (60)	26 (92.9)	19 (40.4)	
Yes	30 (40)	2 (7.1)	28 (59.6)	
Continued BUP until delivery				0.050
Yes	68 (90.7)	23 (82.1)	45 (95.7)	
No	7 (9.3)	5 (17.9)	2 (4.3)	

Data are n (%). Significant at p-value < 0.05.

*BUP, buprenorphine.

**Excludes not reported observation in chisquared tests.

[†]Self-reported race by patient as documented in medical record. Identifiers include Native American or Alaska Native, Asian, Black or African American, Native Hawaiian or other, white, Hispanic, not reported. Only included categories that individuals identified with in the table.

[‡]Insurance information was abstracted upon initial encounter. For those incarcerated, if they were seen outpatient initially, they were charted as having jail insurance (noted in the "other" insurance category). However, if they were seen inpatient initially, they remain on Medicaid and were thus charted as having Medicaid.

[§]Conditions include ADD/ADHD, anxiety, bipolar/mania, depression, schizophrenia, PTSD, other.

[‖]Co-occurring substance use disorders include cocaine, benzodiazepine, cannabis, amphetamine.

[¶]Non-parametric equality of means test used to assess differences between those who were incarcerated at BUP initiation and those who were not.

as an opportunity for MOUD. Our findings highlight how harnessing this opportunity may be enhanced *via* community or academic partnerships. Overall, more research is needed to evaluate outcomes for various methods of delivering MOUD to incarcerated people to optimize OUD care and inform policies impacting this vulnerable population.

Despite the recommendation that MOUD be provided to all patients with OUD regardless of incarceration status, actual

MOUD provision varies widely between incarceration facilities (15). Legislation is greatly needed to standardize this care (5). Interruptions in Medicaid coverage between incarceration and release likely contribute to this important public health issue (6). Notably, many incarcerated patients in our sample were without Medicaid coverage at the time of BUP initiation, reflecting missed opportunities for these individuals to gain coverage in our Medicaid expanded state. Such interruptions in OUD treatment increase the risk for recurrence of use and other adverse outcomes, as patients may be at high risk of overdose when released from incarceration without continuity in MOUD provision. Legislation to cover immediate Medicaid coverage upon reentry, or even ongoing coverage during incarceration, could potentially prevent such gaps in care and facilitate continuity of MOUD treatment. Additionally, the provision of MOUD to incarcerated persons could, in turn, increase treatment engagement in the community upon release, ultimately improving health and psychosocial outcomes (19).

The goal of this study was to examine BUP continuation rates at delivery in pregnant patients who initiated BUP while incarcerated versus not incarcerated. Our results in the context of this existing literature support that, while incarceration is not a recommended addiction treatment pathway, incarceration can serve as an important entry point for OUD care during pregnancy. Additionally, carceral-academic partnerships, in some settings, may improve continuity of care for pregnant and parenting people with OUD. Study limitations include information bias due to the use of the medical records as the data source, rather than primary data collection. Additionally, the patient perspective of treatment and the OBGYN-Addiction program partnership was not evaluated, an area for future investigation. The replicability of the results are unknown due to the small sample and are unadjusted, so results should be interpreted as preliminary. At our institution, pregnant individuals who are transported from local jails must be admitted to the hospital for inpatient observation for BUP initiation. We recognize that this may have generated a sampling bias and may not be a feasible option for other healthcare centers.

Study findings suggest that pregnant individuals receiving MOUD can achieve similar treatment outcomes regardless of incarceration status. The incorporation of an incarceration-based MOUD program partnered with an OBGYN-Addiction program affiliated with an academic health system is feasible and potentially shows preliminary effectiveness at increasing use of life-saving treatments for pregnant individuals seeking OUD recovery. Ultimately, further work is needed to expand access and MOUD continuity for pregnant and postpartum individuals experiencing incarceration. Future studies should evaluate different modes of BUP utilization for incarcerated people to investigate how incarceration status impacts OUD treatment trajectories for this unique patient population.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by the Virginia Commonwealth University IRB. The patients/participants provided their written informed consent to participate in this study.

Author contributions

AN: conceptualization, writing – original draft, and writing – review and editing. HS: data curation, formal analysis, and writing – review and editing. CS: conceptualization and writing – review and editing. BT: conceptualization, methodology, and writing – review and editing. AK: visualization and writing – review and editing. CM: conceptualization, methodology, project administration, supervision, writing – review and editing, and funding acquisition. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Pregnant individual's lived experience of cannabis use during the COVID-19 pandemic: a qualitative study

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Introduction: Quantitative studies indicate that the COVID-19 pandemic has contributed to increased rates of prenatal cannabis use. However, little is known about how the pandemic has impacted cannabis use from the perspective of pregnant individuals themselves. Our objective was to characterize COVID-19-related changes in cannabis use among pregnant individuals who used cannabis during the pandemic.

Methods: We conducted 18 focus groups (from 11/17/2021 to 12/17/2021) with Black and White pregnant individuals aged 18+ who self-reported prenatal cannabis use during universal screening at entrance to prenatal care (at ~8 weeks gestation) in Kaiser Permanente Northern California. Virtual focus groups were transcribed and analyzed using thematic analysis.

Results: The sample of 53 pregnant individuals (23 Black, 30 White) was 30.3 years old (SD=5.2) on average, and most (70%) self-reported daily versus weekly or monthly prenatal cannabis use. Major themes regarding the impact of the pandemic on cannabis use included increases in use (resulting from depression, anxiety, stress, boredom), and changes in social use (less sharing of smoked cannabis products), modes of use (from smoking to other modes due to respiratory concerns) and source (from storefront retailers to delivery).

Conclusion: Coping with mental health symptoms and stress were identified drivers of perceived pandemic-related increases in prenatal cannabis use in 2021. Pregnant individuals adapted their use in ways consistent with public health recommendations to decrease social contact and reduce or quit smoking to mitigate COVID-19 transmission and harms. Proactive, mental health outreach for pregnant individuals during future pandemic waves may reduce prenatal cannabis use.

KEYWORDS

marijuana, cannabis, COVID-19, pandemic, focus group, pregnancy, prenatal

1. Introduction

Cannabis is the most commonly used federally illicit substance during pregnancy, and the prevalence and frequency of prenatal cannabis use have increased in recent years (1, 2). Epidemiologic studies have found that prenatal cannabis use is elevated among pregnant individuals with diagnoses of nausea and vomiting, depressive disorders, anxiety disorders, and trauma (3, 4). Existing qualitative studies indicate that pregnant individuals self-report using cannabis as a way to cope with medical and mental health symptoms, including pain, sleep problems, morning sickness, stress and depressed mood (5–7). Rising rates of prenatal cannabis use are a significant public health problem (1, 2, 8, 9). Cannabis use during pregnancy is associated with potential health risks, including low birthweight and potential neurodevelopmental problems for offspring exposed *in utero* (10–14).

The COVID-19 pandemic, which started in the Spring of 2020, has resulted in increased psychological distress, depression, and substance use among US adults (15–19). Pregnant individuals have faced unique pandemic-related challenges, including major changes to prenatal care, difficulty obtaining childcare, and concerns about the impact of COVID-19 on their pregnancy (20–24). Recent research suggests that rates of cannabis use during pregnancy have increased during the COVID-19 pandemic (25), and pregnant individuals may be using cannabis in an attempt to cope with pandemic-related mental health symptoms. However, qualitative studies that highlight how the pandemic has impacted prenatal cannabis use from the perspective of pregnant individuals themselves are lacking.

To address this gap in the literature, we conducted focus groups at the end of 2021 with Black and White pregnant individuals who self-reported cannabis use during early pregnancy in California, where cannabis is fully legal for adults over the age of 21. Results from these focus groups allow us to understand the impact of the pandemic on individuals with lived experience of prenatal cannabis use.

2. Materials and methods

The study took place in Kaiser Permanente Northern California (KPNC)'s large multispecialty healthcare system serving >4.5 million diverse members (26), and was approved by the KPNC Institutional Review Board. English-speaking pregnant adults aged ≥18 who self-reported non-Hispanic Black or non-Hispanic White race/ethnicity in the electronic health record and self-reported any cannabis use since pregnancy on the self-administered Prenatal Screening Questionnaire as part of universal screening done at entrance to prenatal care (at ~8 weeks gestation) were eligible; those who used daily or weekly were prioritized for recruitment. For this initial study we selected pregnant individuals who were non-Hispanic Black or non-Hispanic White because they constitute the racial/ethnic groups with the highest prevalence of prenatal cannabis use in our healthcare system (27). We did not utilize electronic health record data on prenatal cannabis use based on routine urine toxicology testing done at entrance to prenatal care because we wanted to recruit participants who were willing to self-disclose prenatal cannabis use and would be more likely to feel comfortable discussing this topic in a focus group setting.

After conducting chart reviews to confirm that the patient had no documented pregnancy loss, patients were sent an email with information about the study and an option to opt out. Potential participants were then contacted by phone and provided verbal informed consent to participate in this study. The KPNC *IRB waived the requirement* to obtain signed consent as the research presented no more than minimal risk of harms to participants and involves no procedures for which written consent is normally required outside of the research context. Patients were informed that participation in the study would be confidential and would not impact their clinical care. During recruitment, patients were asked if they were still using cannabis and if not, the date when they stopped using.

We developed a semi-structured focus group script that included multiple domains, including reasons for prenatal cannabis use, perceived harms, changes in use during pregnancy, and communications with clinicians about prenatal cannabis use. Participants were asked whether they think pregnant women are more likely to use cannabis now than they were 5 years ago and why or why not. Interview probes included the COVID-19 pandemic and individuals could respond about what they have seen among pregnant individuals in general or respond about their own cannabis use behaviors (Supplement). The semi-structured format and allowed for new themes to emerge. HIPAA-compliant virtual focus groups took place *via* video-conferencing software (Microsoft Teams) from 11/17/2021 to 12/17/2021. Participants were encouraged, but not required, to have their cameras on during the focus group. We chose to match focus group leaders and participants on race, with recognition that people with shared experiences may be more open with each other (28, 29), and to acknowledge the role that race/ethnicity plays in the experiences of pregnant individuals. Individuals received a $50 gift card for participating. The study team had weekly meetings to review field notes and to discuss emerging themes. After 18 groups, thematic saturation was achieved. Focus groups were recorded and professionally transcribed. Video and audio were deleted after transcription was completed.

A thematic analysis approach was used to analyze the transcripts. First, three members of the team (KYW, TF, AA) created a codebook after reviewing all transcripts. Next, study team members (KYW, TF, AA, EI, MD) independently coded two transcripts, and the team further refined the code book to reach consensus on themes and subthemes. The remaining 16 focus groups were manually coded by the study team using NVivo Qualitative Analysis Software (Release 1.6.1). Quotes related to the impact of the COVID-19 pandemic were selected for this study and transcripts were compared for potential differences in responses by participant race. Additional details about the focus group methods appear elsewhere (30).

Descriptive statistics (frequencies, proportions, means) were used to summarize patient socio-demographics, frequency of prenatal cannabis use, whether participants had quit using cannabis at the time of recruitment, and trimester participants quit using cannabis among those who had stopped using.

3. Results

Of 304 eligible patients, 139 were unable to be reached, 53 refused, 2 were found to be ineligible, 5 had time conflicts, and 1

TABLE 1 Characteristics of focus group participants (*N*=53).

Participant characteristics	*N*	%
Age categories		
21–25	11	20.8
26–30	19	35.8
31–35	13	24.5
36–40	10	18.9
Race		
Black	23	43.4
White	30	56.6
Trimester at phone screening		
1st	9	17.0
2nd	25	47.2
3rd	19	35.8
Frequency of self-reported cannabis use during pregnancy		
Daily	37	69.8
Weekly/Monthly	16	30.2
Trimester the participant stopped using cannabis		
1st	31	58.5
2nd or 3rd	6	11.3
N/A – still using	16	30.2

did not complete the consent process. Of the 104 individuals who were scheduled for a focus group, 51 did not participate (39 did not show up, 10 canceled, and 2 had groups that were canceled by the group leader) and 53 participated in one of 18 focus groups, including 23 Black individuals and 30 White individuals. The average length of the 18 focus groups was 73.4 min (range 42–92 min) and the number of participants in a focus group ranged from one to six.

Descriptive information is provided in Table 1. The sample ($n = 53$) had a mean age of 30.3 (SD = 5.2) years, 17.0% were in their first trimester, 47.2% were in their second trimester, and 35.8% were in their third trimester at the time of recruitment. At entrance to prenatal care, 69.8% self-reported daily cannabis use and 30.2% reported weekly or monthly or less cannabis use since pregnancy. The median (interquartile range) time from the first prenatal visit to the phone screening was 15.1 weeks (7.6–21.7). Most (69.8%) reported that they had quit using cannabis at the time of study recruitment. Of those who quit, 83.8% quit in the first trimester and 16.2% quit during the second or third trimester.

We identified six themes related to the COVID-19 pandemic in the following two domains: (1) Impact of mental health and isolation/boredom on cannabis use during the pandemic, and (2) Changes in specific cannabis-related behaviors. Themes were consistent across focus groups with Black and White participants, although comparatively fewer Black participants discussed the impact of the pandemic than did White participants.

3.1. COVID-19 related changes in prenatal cannabis use

3.1.1. Mental health-related increases in cannabis use

Many participants described how the COVID-19 pandemic has led to greater cannabis use during pregnancy. Increased psychological and financial distress, depression, and anxiety were identified as drivers of COVID-19 related increases in cannabis use. One participant noted, "COVID, the pandemic itself was really stressful, and I feel like even people not pregnant, they using you know cannabis to help with the stress …. I feel like everybody gonna have like some type of PTSD from all of this." Another highlighted the impacts of financial distress resulting from the pandemic: "So for those people who were not working or the stress of the money, and I know the economy was really a mess for a while …. I think that might have heightened cannabis usage just in people trying to relax, calm down, take a breather, and not have to deal with the intenseness of COVID, especially at the height of it."

Several participants described how the impacts of the pandemic on cannabis use changed over time. One participant who was pregnant twice during the pandemic described how changes in her pandemic-related anxiety differentially impacted her cannabis use during her first versus second pregnancy, noting: "[During my first pregnancy] my reasoning for smoking was to help me wind down from my workday, and I wasn't attending work as much, and I was just able to stay home, so I actually did not feel like I needed it. Whereas my second pregnancy now, I am back at work, but we have these masks, and some people aren't vaccinated, I'm definitely sensing a lot more anxiety this time around …. so it's been a lot harder to quit cannabis this time around." Several participants noted that cannabis use was most affected during the early months of the pandemic. One reported, "I think the pandemic does increase use of cannabis during pregnancy. Maybe not this far into COVID but I think especially early on when quarantine was a lot more serious, and people who are social and do recharge their batteries by being social were having to be isolated and depression was an even bigger issue. Or people becoming very anxious and going stir crazy being stuck in the house, and then finding out oh, I'm pregnant, and all these things that I would have wanted to do during pregnancy, I cannot do. So, becoming a coping mechanism."

3.1.2. Isolation/boredom-related increases in cannabis use

Some participants reported that isolation and boredom resulting from pandemic-related social-distancing measures contributed to increases in cannabis use during the COVID-19 pandemic. One participant described: "I think that, yeah, the pandemic leads more people to using cannabis because it's something to do and being stuck at home during quarantine definitely sucked. I work from home. I still have those days where I'm like, 'I just need to go out and do something. I have nothing to do at home that I want to do'." Another noted: "I'm one of the type of people that it's hard for me without a routine. So, I'm definitely more likely to smoke more, to drink more if I'm still at home, which I am."

Participants also highlighted the unique challenges of the pandemic for pregnant individuals who are already advised to monitor or change their health behaviors as part of standard obstetric care. One reported: "[With the pandemic] going on like 2 years now, where

you might be [in a routine of] drinking more at home or smoking more at home, and your whole life has changed, it's harder to get out of, we are already so limited. We've been so limited now. And during pregnancy, you are supposed to be even more limited. So, I think that would make it even more difficult [to quit cannabis use during pregnancy], you know, once you are into those new routines."

3.1.3. Little impact or decreases in cannabis use

Conversely, some participants described how the pandemic had little impact on cannabis use or even helped them to abstain from using cannabis. One woman emphasized how the experience of being pregnant transcends any impacts of the pandemic: "I think prenatal cannabis use would be the same if there wasn't a pandemic because women are still going through the same issues regardless of a pandemic or not. Building a baby inside of you does not change because the world is falling apart around you. That has nothing to do with it. It might slightly impact the way you are handling things around you so maybe that could add some extra stress and anxiety, but I do not necessarily think that being in a pandemic has changed the troubles of being pregnant." Another noted that social distancing resulting from the pandemic has made it easier for her to abstain from cannabis use during pregnancy: "I've been lucky that you know, with the pandemic, I have not been around friends and family smoking. And I know that it would be a big struggle for me if I was smelling it and watching it. The biggest thing that makes me want to smoke is watching other people smoke, even if they are smoking cigarettes, it makes me want to do the act of smoking."

Some participants reported that their cannabis use during pregnancy was not impacted by the pandemic because they were not pregnant during the height of the pandemic. For example, one participant stated, "It [the pandemic] did not really change anything for me. Like my pregnancy kind of started after the height of COVID. Yeah. So I do not really feel like it affected it at all." Another discussed how her cannabis use increased during the first year of the pandemic prior to her pregnancy: "I was sitting at home, and I was bored…. And it was like, 'Oh, I can do this. Like, I'm here! I could sit here. I could eat all day. I could smoke all day. I'm here for a whole year.' I definitely was smoking more, like that whole entire year. Definitely. But I wasn't pregnant."

3.2. COVID-19 related changes in cannabis use behaviors and source of cannabis

3.2.1. Changes in sharing smoked cannabis products

A few participants described how they stopped sharing smoked cannabis products (e.g., pipes, joints, etc.) due to concerns about COVID-19. One noted: "We stopped sharing joints because we did not know. We did not know the risks. We did not know how easily it could spread….So, I mean, if it affected anything, it maybe just made us a little more cautious in sharing things…. If we'd still get together and smoke, we would just use our own things and not share because you never know." Others described how they returned to pre-pandemic sharing behaviors after their friends were vaccinated. One noted: "I think before we got vaccinated, we were like, 'Nah, we do not want to share with you.' Now, all of our friends are vaccinated, like now we do not really care as much."

3.2.2. Changes in mode of cannabis administration

Several participants perceived smoking to be a risk factor for COVID-19 and reported switching from smoking cannabis to other modes of cannabis administration that they viewed to be safer with regard to COVID-19. One noted: "And I know that people who smoke any kind of anything can be more at risk for COVID-19. So, for me, I switched over to different methods just because I felt safer." Another described: "You have the people who are overly concerned about their health and do not want to cause any sort of detriment to their lungs if COVID-19 is a respiratory illness that's going around….If you are concerned about the respiratory effects, then you would just choose to maybe do edibles instead."

3.2.3. Changes in source of cannabis products

Some described how concerns about the increased risks of COVID-19 during pregnancy led them to change their source of cannabis products. For example, one participant described switching from purchasing cannabis at a retailer to doing home delivery: "I started doing more home delivery services, as opposed to going to a dispensary just because I did not want to be surrounded by people….I had talked to my doctor about the heightened risks of getting sick while pregnant – I went out of my way to avoid being around more people if I could help it."

4. Discussion

This timely focus group study characterizes the impact of the COVID-19 pandemic on cannabis use from the perspective of pregnant individuals who used cannabis during early pregnancy. Participants generally perceived that pregnant individuals are more likely to use cannabis during the pandemic, primarily driven by increases in anxiety, depression, isolation and boredom. Participants identified cannabis use as a coping mechanism and described how pandemic-related increases in prenatal cannabis use corresponded directly with changes in pandemic-related stress. Similar increases in cannabis use as a result of coping with COVID-19-related emotional and psychological distress have been found in qualitative studies of other vulnerable populations, including young adults (31), and our findings complement prior research showing that pregnant individuals report using cannabis to cope with medical and mental health symptoms during pregnancy (5–7).

Prior studies have shown that the pandemic has had a major impact on pregnant individuals, resulting in increases in depression, anxiety, loneliness, COVID-19-specific worries related to the potential health effects of the COVID-19 on their pregnancy, and concerns about changes to prenatal care (e.g., lack of a support person during delivery) (21, 22, 32). Studies examining the impact of the COVID-19 pandemic on substance use during pregnancy have found that depression symptoms and financial difficulties are associated with a higher likelihood of cannabis use and polysubstance use during pregnancy (33). Recent electronic health record data have documented an increase in rates of prenatal cannabis use from before to during the pandemic (25), and findings from this focus group study provide insights into the potential

mechanisms underlying pandemic-related increases in cannabis use during pregnancy.

Importantly, for some, the COVID-19 pandemic had little impact on their likelihood of using cannabis, and for others the isolation of the pandemic provided an ideal respite from common risk factors/triggers for cannabis use (e.g., seeing others smoke). Importantly, some patients felt that their cannabis use behaviors during pregnancy were not impacted because they were not pregnant until later in the pandemic. This perception aligns with research indicating that frequency of cannabis use and self-reported mental distress among US adults increased during the early months of the pandemic and then returned to baseline levels (34). While the study took place more than one and a half years into the pandemic (November and December 2021), the WHO designated the COVID-19 Omicron variant as a "variant of concern" on November 26, 2021, due to increased transmissibility (35), and the potential for another surge. Yet, many participants spoke about the pandemic in the past-tense, or described getting pregnancy after the pandemic, suggesting that most felt like the greatest impacts of the pandemic were behind them. Participants tended to report on COVID-19 related changes in patterns of or reasons for prenatal cannabis use that are applicable to other populations (e.g., stress-related increases in use), rather than on pregnancy-specific impacts (e.g., concerns about potential impacts of COVID-19 on the fetus). It is possible that individuals who were pregnant earlier during the pandemic may have had different experiences and potentially more responses specifically relating to the interaction of the pandemic and pregnancy.

Our findings also highlight how pregnant individuals who used cannabis early in pregnancy adapted their cannabis use behaviors to reduce potential harms, by not sharing cannabis smoked products, switching to non-smoked modes of administration, and changing to delivery vs. entering storefront retailers. These changes in cannabis-related behaviors are consistent with other research in non-pregnant populations (36), and support the notion that pregnant individuals are motivated to live healthier lifestyles to improve the health of their developing child.

4.1. Limitations

This study has several limitations. Our sample included pregnant non-Hispanic Black and non-Hispanic White individuals in KPNC, and nearly all reported self-reported daily or weekly (versus less frequent) cannabis use during early pregnancy. Future studies with participants of other racial/ethnic groups, uninsured individuals, and those with less frequent cannabis use during pregnancy, and those living in states where cannabis is not legal are needed to better understand pregnant individual's perspectives of how the pandemic impacted cannabis use. In addition, consistent with studies showing that cannabis use is highest among pregnant individuals during the first trimester, most participants in our sample reported that they had quit using cannabis at the time of study recruitment, and we are unable to determine whether their self-reported use since pregnancy was only prior to pregnancy recognition. Additional studies are needed to understand the extent to which the COVID-19 pandemic impacted whether pregnant individuals quit or continued cannabis use during pregnancy. Finally, individuals who were willing to participate in the focus group study may have unique perspectives that may not generalize to those who were eligible but were unreachable or chose not to participate; however, we note that focus group studies are not meant to be generalizable and are intended to be hypothesis generating.

5. Conclusion

The current study adds novel qualitative data suggesting that increased depression, anxiety, isolation and boredom are perceived drivers of pandemic-related increases in prenatal cannabis use. Results highlight the need for strategies and programs that combat these issues to potentially decrease prenatal cannabis use and increase positive coping. Most pregnant individuals have regular contact with a healthcare system, even during the COVID-19 pandemic, and clinicians and healthcare systems can help to support pregnant individuals by providing non-judgmental information about the health effects of prenatal cannabis use, taking time to understand reasons for cannabis use, and linking pregnant patients with resources tailored to their specific needs. Further, early comprehensive, and routine screening for prenatal anxiety and depression during the pandemic, along with linkage to resources and interventions, may hold promise for helping pregnant individuals cope with the significant mental health impacts of the pandemic in ways that do not involve cannabis use. Finally, results underscore the impact of social distancing on pregnant women, and suggest that group-based prenatal care, and public health interventions that offer suggestions and strategies for combatting isolation in future pandemic waves may be particularly beneficial.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving human participants were reviewed and approved by The Kaiser Permanente Northern California Institutional Review Board. Patients provided verbal consent and the ethics committee waived the requirement of written consent for participants.

Author contributions

TF, AG, EI, and KY-W created the interview guide. TF and AG led the focus groups. AA, TF, and KY-W developed the coding scheme. AA, TF, EI, KY-W, and MD reviewed and coded the transcripts. KY-W drafted the manuscript and obtained funding. All authors provided critical revisions to the manuscripts and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Usability and acceptability testing of a Plan of Safe Care in a mobile health platform

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Purpose: Women who are pregnant or parenting while recovering from substance use disorder (SUD) are at risk for insufficient recovery support. With the federal mandate, implementation has been left to each state for the Plan of Safe Care (POSC), leading to challenges in providing comprehensive care coordination and meeting federal reporting requirements.

Methods: This research tests the usability and acceptability of a POSC platform, called SAFE4BOTH, which combines a mobile health (mHealth) app for use by mothers with substance use disorder (MSUD) with a web-based case management system for use by stakeholders to reduce the issue of fragmented postnatal maternal and infant care. The platform was designed to enable access to services, improve reporting task workflow, and assist in improving interactions between mothers and service providers.

After applying a user-centered design approach, the usability and acceptability of the SAFE4BOTH platform were evaluated using focus groups, interviews, and a System Usability Scale (SUS). The evaluation involved four staff members from a Medication for Addiction Treatment clinic (comprising of three case management workers and one peer counselor), four state employees of the Delaware Division of Family Services, and 20 mothers with MSUD who had delivered infants in need of a POSC.

Features tested in the SAFE4BOTH platform included a secure, web-based POSC, a contingency management-based reward system, a micro-learning library, a resources locator, a chat messaging and videoconferencing system, a directory for contact management, a QR code reader, use of an appointment compliance system engaging geofencing, and an enhanced calendar. Family services and treatment center staff accessed SAFE4BOTH from their laptops or tablets, and MSUD accessed SAFE4BOTH from their phones.

Results: Family services staff, treatment center staff, and MSUD participants rated SAFE4BOTH as usable and acceptable with average System Usability Scale scores of 68.1 (SD 8.5), 92.5 (SD 11.73), and 78.4 (SD 12.5) (respectively).

Conclusion: The platform was judged both usable and acceptable by all three target populations (family services staff, treatment center staff, and MSUD). Further studies are planned to explore the efficacy of longitudinally supporting the mother's recovery and the infant's healthy development.

KEYWORDS

substance use disorder, opioid use disorder, web-based case management, Agile, mHealth, contingency management, user-centered design, usability testing

Introduction

According to the 2021 National Survey on Drug Use and Health, approximately 16.4% of females aged 18–44 reported past-month illicit drug use, and 49.9% reported past-month alcohol use (1). Over 19,300 babies were diagnosed with neonatal abstinence syndrome/neonatal opioid withdrawal syndrome (NAS/NOWS) at birth during the same period (1–3). Aggregate hospital charges for NAS, a frequent result of opioid exposure, increased from $732 million to $1.5 billion in 2014, with 81% attributed to state Medicaid programs (4). Women who use illicit substances are likely also to be using alcohol and tobacco and struggling with traumatic personal histories (5). Additionally, they require comprehensive behavioral health care and coordination of services, especially during and after delivery (6–9). These mothers may also be more likely to experience emergency room visits and hospitalizations in the antenatal period and less likely to receive prenatal care (10).

The 2016 Comprehensive Addiction and Recovery Act and the recently updated Child Abuse Prevention and Treatment Act (11) require states to provide a Plan of Safe Care (POSC) for mothers who are at risk of relapse or unsafe conditions for their infants due to maternal substance use. With minimal requirements given by the federal government regarding the reporting and data requirements for the POSC, each state and local jurisdiction is responsible for creating its POSC. At a minimum, the states or jurisdictions must create and maintain a POSC to verify the mother is continuing her substance use disorder (SUD) care, confirm that infants are being discharged to a safe environment, and ensure the infants are being taken to regular well-baby visits (12). Each year, between 12,000 and 240,000 women are expected to need a POSC (13). However, the current state and local systems are not equipped to manage the unique challenges the federal mandate requires, and there is concern over how the law's intended spirit of keeping infants and mothers safe will be enacted.

The level of oversight in a POSC requires significant funds, coordination, collaboration, and case management to facilitate integration across multiple state or local agencies, healthcare providers, and caretakers (8, 14). The economic burden of caring for mothers with SUD (MSUD) during and after pregnancy and their infants or children can be significant (15, 16). MSUD are at risk of insufficient support to provide care for their infants' physical, emotional, and safety needs. Appointment compliance (17) can be a critical proxy measure to determine whether the mother is engaging in the healthcare system after delivery and progressing in her recovery.

Based on our qualitative work, a mobile health (mHealth) platform consisting of a web-based case management system for family services and treatment center staff and an app for the mothers (i.e., SAFE4BOTH) was developed to help MSUD adhere to their POSC plan after delivery. The goal of the SAFE4BOTH platform is to reduce fragmented prenatal and postnatal maternal and infant care for MSUD and improve interactions between MSUD and family services and treatment center staff. This study reports the findings of the usability testing of SAFE4BOTH with the target population of MSUD and staff at local and government agencies recruited in the mid-Atlantic region.

Materials and methods

Design

As described earlier, extensive formative research supported a user-centered design process completed with MSUD and family services and treatment center staff prior to the creation of the mHealth platform (18). It was determined that significant barriers to an efficient workflow were a lack of communication between family services staff, treatment staff, and the mothers, poor appointment adherence (frequently caused by a lack of transportation or childcare), and difficulties with maintaining updated contact information. Contingency management or rewards (points earned in exchange for items from a donation center in return for verified appointment adherence or completing educational materials) were very popular features with the mothers and, as such, were incorporated into the mHealth app design.

Recruitment

Staff from the Delaware Division of Family Services-Department of Services for Children, Youth, and Their Families, and the Delaware-based CORAS Wellness & Behavioral Health (formerly Connections Treatment Center) organization were asked to use the web-based case management website component of the SAFE4BOTH platform for family services and treatment center staff. Mothers were approached within 24 h of delivery at the ChristianaCare (Newark, DE) Labor and Delivery, Pediatric, and Maternity Units if their infants were under observation for NAS/NOWS and were asked to use the mHealth app component of the SAFE4BOTH platform. MSUD were eligible to participate in the study if they met the following criteria: their age was between 18 and 44, they had delivered an infant who was diagnosed with NAS/NOWS and therefore required a POSC, were English speaking, residing in Delaware, were not ill and the infant was going to go home with the mother. ChristianaCare provided the IRB for this study.

Usability testing

Staff members tested the platform's ability to provide instant access to the current web-based POSC, to verify appointment attendance, easy access to federally-mandated automated summary reports for family services and treatment center facilities, in-app text messaging and videoconferencing, a video library with educational materials tailored to MSUD, an in-app contact list for all relevant stakeholders, and a contingency management mechanism to reward

MSUD for viewing educational materials delivered on their mobile devices.

Usability testing for family services and treatment center staff was conducted with the SAFE4BOTH prototype in July–September 2021 using think-aloud (19) testing sessions at their facility. Each family services staff person ($n = 4$) or treatment center counselor ($n = 4$) was paired with program staff from Benten. During the testing session, Benten staff played the role of an MSUD who had recently given birth. A script was provided to assure that the most significant components of the case management within the SAFE4BOTH platform were tested over a single 60–90 min session and testers were asked to 'think aloud' as they were using the web-based case management system and comment on their thoughts of the design and processes as they used the Case Management System to complete the tasks requested in the script.

After completing eligibility questions and informed consent, MSUDs were asked to download and meet with the research coordinator to go through a script with a prescribed set of tasks. It could take up to three sessions to complete the intake and usability testing, depending on the time the mother had available while in the maternity ward. She was allowed to use the app and continue going through the script on her own between research coordinator visits. The MSUD script required the mothers to use in-app text messaging and videoconferencing, a video library with educational materials tailored to MSUD, an in-app contact list for all relevant stakeholders, and a contingency management system that included a wish list for future items to be purchased with points earned from watching the videos, taking quizzes and updating their contact information.

Assessment instruments and usage measures

After the sessions, participants rated the design using the System Usability Scale (SUS) survey instrument (20, 21), which included three additional open-ended questions about the usability and acceptability of the design. The SUS is a widely used and validated scale; the scale can be employed to evaluate a variety of technologies (e.g., web and mobile applications) and provides a score to evaluate the perceived usability and acceptability of the two main components of SAFE4BOTH, namely the mobile app for mothers and web-based case management for staff.

Participation in the testing was voluntary and treatment center staff members were given $25 gift cards in compensation. After completion of the usability testing, MSUD completed a SUS survey which included three open-ended questions and were given a $60 gift card in compensation. Usage data was automatically captured from the app and obtained from the server to assess user engagement with SAFE4BOTH's mobile app for mothers.

Results

Pilot testing with family services and treatment center staff of the web-based platform

A total of four family services and four treatment center staff completed the testing of the web-based case management system (see Table 1), and all participants completed a SUS to rate the prototype SAFE4BOTH platform. The family services staff rated the SAFE4BOTH's case management platform system as "HIGH MARGINAL" for acceptance and usability (68.10, SD 8.50) and in the "OK" range for adjective ratings, while the treatment center staff rated the SAFE4BOTH platform as "ACCEPTABLE"—"BEST IMAGINABLE" range (92.50, SD 11.73) (see Figure 1).

Although the family services staff members' SUS scores were in the HIGH MARGINAL range, all four family services participants responded that they would want to use the platform if it was available, and this positive attitude is reflected in the representative comments displayed in Table 2.

Pilot testing of the mobile health app with MSUD

Of the 94 women who were approached over the 17 months (March 2021–July 2022), 29 women completed the informed consent and were enrolled in the pilot. The reasons why some women were not enrolled included being COVID-positive at delivery ($n = 3$), no diagnosis of NAS in the infant (so no POSC was required, $n = 5$), out-of-state residence ($n = 13$), no fluency with English ($n = 3$), incarceration ($n = 2$) or no interest ($n = 5$). Numerous women expressed an interest at the first contact but then failed to respond to future outreach attempts ($n = 27$). Eight of nine women who did not complete the testing did not return phone calls or in-app text messages. Three attempts over 2 weeks were made to re-engage the mothers, at which point they were dropped from the study. One mother reached back out to the research coordinator and informed her that she was no longer interested in participating and so was marked as 'withdrawal'. As such, of those 29 who were enrolled, 20 completed the pilot study. The demographics of the women who completed the pilot testing are in Table 3.

MSUD participants were given a script for activities to complete. Out of the ten features of the application listed in the script, all participants ($n = 20$) completed the testing script, used the videoconferencing feature with the assigned staff, and then completed a SUS. The MSUD participants gave the application a SUS of 78.4 (SD 12.5), which is equivalent to an ACCEPTABLE-GOOD rating (see Figure 2).

A closer look at the specific SUS responses revealed that an overwhelming majority of the women found the application easy to use (95%) and were confident they could master its features (90%). In addition, 75% were looking forward to using this application in the future and 80% would consider downloading the application if it were available (see Table 4).

A review of the open-ended questions where the women were asked to list the three features they liked most about the app supported

TABLE 1 Demographics for family services and treatment center staff.

Group	Hispanic/Latino	Racial category
DFS staff ($n = 4$)	4 Non-Hispanic/Latino	3 White and 1 more than one race
MAT ($n = 4$)	4 Non-Hispanic/Latino	3 White and 1 Black

FIGURE 1
System usability scores (SUS) from family services and treatment center staff after usability testing.

TABLE 2 Representative family services and treatment center staff responses to open-ended questions after usability testing.

Delaware Division of Family Services (DFS) Staff	• *I think the application is a great way to keep all the information organized and in one place and being able to see progress in the MAT programs. (DFS03)* • [I liked the] *easy communication with moms and [being] able to track follow-up appointments (DFS08)* • [I liked the] *time line on the dashboard (DFS04)* • [I found it] *easy to use overall (DFS02)*
Medication for Addiction Treatment (MAT) Center Staff	• [The SAFE4BOTH platform provides a] *central way to track who's POSC has and has not been completed and* [is a] *MUCH easier way to fill out the POSC* versus *a word document which can be frustrating (MAT07)* • *I love this system. I'm sure it will help us all communicate the needs of the mothers and babies much better as well! (MAT10)* • [My three favorite features were the list of outstanding] *tasks, timeline and wish list (MAT04)* • [I liked the] *ability to see if clients attended appointments (MAT05)*

TABLE 3 Demographic information for MSUD participants.

	Percent
Race/ethnicity	
White	14/20 (70%)
Black or African American	6/20 (30%)
Non-Hispanic/Latino	19/20 (95%)
What is the highest grade you finished in school or through home-schooling?	
Grades 9–11	4/20 (20%)
High school graduate (12th grade)	7/20 (35%)
Junior college degree	1/20 (5%)
Some college	7/20 (35%)
Some post-college work	1/20 (5%)
Total	20 (100%)
Age group	
25–29	3/20 (15%)
30–34	13/20 (65%)
35–39	3/20 (15%)
40–44	1/20 (5%)
Total	20 (100%)
Number of mothers with more than 1 child	18/20 (90%)

the conclusion that the women saw this application as valuable and useful (see Table 5).

The most popular feature was the educational materials, followed by the ability to easily schedule appointments using the contacts and calendar elements and the built-in reward system. Several mothers identified the enhanced communication options through the chat and video call features as important to them. Two specifically mentioned that easy access to their POSC was one of the top three critical features they liked in the app. Additional responses related to what the women would like to see improved in the app (such as more options in the rewards "shop", additional features in the text and video chat elements, and more content in the microlearning/resources section) will be used to drive the revisions to the design of the app in future iterations.

The MSUD responses to the open-ended questions in the SUS reflected their positive attitude towards the app in general (see Table 6).

Discussion

Overview

The current report describes the newly developed SAFE4BOTH platform and usability and acceptability testing with family service and treatment center staff members and MSUD. The SAFE4BOTH platform was rated usable and acceptable by both MSUD as well as the family services and treatment center staff members. The platform

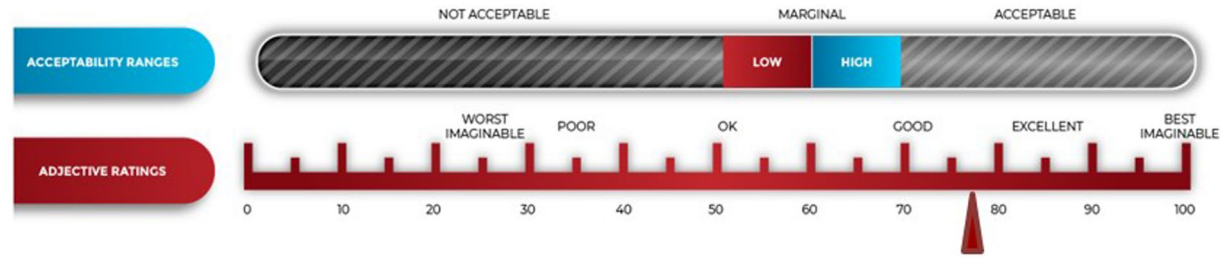

FIGURE 2
System usability scores from mothers with SUD.

TABLE 4 A detailed review of the MSUD participants' SUS responses after usability testing.

Question	Strongly agree/ agree	Neutral	Strongly disagree/ disagree
I think that I would like to use this mobile application frequently	15 (75%)	2 (10%)	3 (15%)
I thought this mobile application was easy to use	19 (95%)	1 (5%)	0
I would imagine that most people would learn to use this mobile application	19 (95%)	0	1 (5%)
I felt very confident using this mobile application	18 (90%)	2 (10%)	0
I would consider downloading the mobile application if it were available	16 (80%)	2 (10%)	2 (10%)

received OK to EXCELLENT ratings for its ability to incorporate educational materials as well as digital and feature-rich case management mechanisms combined with a mobile-based POSC with a reward system to improve coordination of care for women who are in recovery with infants exposed to substance use during gestation. The MSUD scored the app as ACCEPTABLE for usability and GOOD in the adjective ratings. Their open-ended responses cited the value of the calendar, communications, and organization. Only two of the 20 MSUDs said they would not download the app if it were available today. Only one expressed concern about difficulties navigating the mHealth app while using it. Several women suggested improvements that will be incorporated into the next version related to making the chat function more user-friendly.

The treatment center staff rated the case management component of the SAFE4BOTH platform as ACCEPTABLE and gave it the BEST IMAGINABLE adjective rating. They repeatedly asked when the platform could be rolled out for use and were excited about the enhanced communication and the ability to monitor appointment compliance. The family services staff rated the acceptability as MARGINAL-HIGH and gave the platform an OK rating. They saw the platform's potential as noted in their comments but seemed reluctant to adopt another notation or tracking system to use with the mothers with SUD. It is unclear at this time why the treatment center staff members scored the platform so much higher than the family services staff. Future research will focus on determining what would make the platform more attractive to family services workers. One possibility for increasing satisfaction with the platform is that when the system is fully integrated with the family service staff's existing case-management software, the need for double data entry will be removed. In addition, when the SAFE4BOTH web-based POSC is readily accessible to all healthcare providers, state-based child welfare employees, and mothers, it will be possible to fill out a large portion of the POSC before delivery when the mother is at a treatment center clinic and can work with a pregnancy counselor, rather than shortly after delivery with a family services staff person. Combining these two additional features (integration and expanded access) will allow for the existence of a substantially pre-filled POSC available for updating at the time of hospital discharge and is expected to significantly reduce the family services staff members' workload. SAFE4BOTH has the potential to greatly improve care transitions from medication for addiction treatment centers for mothers with SUD to birth hospitals to homes (22).

Revisions to the original pilot protocol

Due to the COVID pandemic and logistical issues related to testing in a clinical setting, modifications had to be made to the original pilot protocol. Case managers at family services and the counselors at the treatment clinics found it very difficult to add platform development testing to their already demanding schedules. In addition, the State of Delaware information technology department's requirements for personal information protection put significant limitations on the usability testing phase. As such, it was determined that for the usability testing, the best approach was to do separate sessions where developers interacted with the users to test the system features using a think-aloud script.

Accessing and recruiting mothers in the hospital on the post-partum floor during the COVID-19 pandemic was also extremely difficult. Frequently, during the height of the pandemic, the mother was discharged within 24 h of delivery while her infant stayed in the hospital under observation. The research study design was revised such that it was possible to brief the mothers who were in treatment at the clinic associated with the hospital before delivery. Then

TABLE 5 MSUD response to "Top 3 most liked app features."

Most liked app features	Mentioned in the free response section
Education and resource materials	12 (60%)
Contacts/appointments /calendars	6 (30%)
Reward system	5 (25%)
Enhanced communication	4 (20%)
Easy access to the POSC	2 (10%)

TABLE 6 Representative MSUD responses to open-ended questions in the SUS after usability testing.

Mothers with substance use disorder	• *I like how you can chat with providers (Mom28)* • *Organized (Mom27)* • *Important contacts and appointments in one place (Mom11)* • *Offers a lot of help/organization/answers to questions (Mom13)* • *The helpful videos (Mom24)* • *I think the rewards points program will influence users to do more (Mom11)* • *Ability to get points and spend them (Mom13)* • *That you could look up the information in regards to your safety plan (Mom25)* • *I'm learning more about the process of my child safety and health (Mom14)*

enrollment, follow-up, and testing were completed when the mothers were visiting their infants.

A final unexpected technical challenge was the inability to download the SAFE4BOTH app to the mother's phone while she was in the hospital. Although the hospital provides free guest Wi-Fi, the bandwidth was too limited to download the app to the mothers' phones. A Wi-Fi system was purchased just for this study to bypass the hospital settings and guest Wi-Fi limitations.

Despite recruitment and follow-up complications due to the COVID-19 pandemic, there were positive outcomes derived from conducting the study during the pandemic. When videoconferencing was initially proposed to meet with the mothers, the family services staff were highly reluctant to adopt this technology rather than in-person home visits. After the pandemic began, they were much more open to the idea. Similarly, while delivering educational content via a mobile phone was considered favorable in the initial stages, it was much more enthusiastically embraced after all in-person educational classes were canceled at the treatment center clinic.

Limitations

There were several limitations to the study design. For this stage of usability testing, the study could only include MSUD who lived in the State of Delaware, as the POSC is specific to the state in which it is implemented. This exclusion criterion excluded mothers from surrounding states such as Pennsylvania. In addition, the study utilized a short usability testing period, typically restricted to the use of a script with a study coordinator in a 1–2 h testing period. In normal circumstances, the app would be expected to be used over a 12-month pre-and post-natal period. As with most app usability studies, the number of MSUD testers was limited to 20. While 20 participants can usually identify 90%–95% of all flaws in an app (23), further testing with larger group sizes will be planned before the product's release.

Conclusion

SAFE4BOTH is among the first mHealth apps with a comprehensive platform that provides integrated care coordination to be used by MSUD, any provider, and staff from state and local government agencies. The utilization of a secure, web-based POSC with a mobile app such as the SAFE4BOTH platform is feasible by families, providers, and child protection agencies and can provide incentives for mothers with SUD to continuously engage in care. By enhancing communication within and between organizations attempting to provide care and support for mothers with SUD, care can be focused on supporting recovery and providing a safe environment. Large population-based studies will be needed to determine if SAFE4BOTH can reduce the risks of adverse outcomes in this high-risk population.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed by ChristianaCare IRB. The patients/participants provided their written informed consent to participate in this study.

Author contributions

KI, EB, ST, YW, DP, KC, and TM contributed to the design of the experiment, participated in the research, and edited the manuscript. TP advised on the design of the original protocol and adaptations to the protocol during the testing. All authors contributed to the article and approved the submitted version.

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Conflict of interest

TM and KC are co-owners of Benten Technologies, the company that is designing this system and will eventually market the SAFE4BOTH product.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Addressing stigma within the dissemination of research products to improve quality of care for pregnant and parenting people affected by substance use disorder

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Substance use disorders are a common and treatable condition among pregnant and parenting people. Social, self, and structural stigma experienced by this group represent a barrier to harm reduction, treatment utilization, and quality of care. We examine features of research dissemination that may generate or uphold stigmatization at every level for pregnant and parenting individuals affected by substance use disorder and their children. We explore stigma reduction practices within the research community that can increase uptake of evidence-based treatment programs and prevent potential harm related to substance use in pregnant and parenting people. The strategies we propose include: (1) address researcher stereotypes, prejudice, and misconceptions about pregnant and parenting people with substance use disorder; (2) engage in interdisciplinary and transdisciplinary collaborations that engage with researchers who have lived experience in substance use; (3) use community-based approaches and engage community partners, (4) address stigmatizing language in science communication; (5) provide contextualizing information about the social and environmental factors that influence substance use among pregnant and parenting people; and (6) advocate for stigma-reducing policies in research articles and other scholarly products.

KEYWORDS

stigma, substance use disorder, dissemination, perinatal, harm reduction, parenting, treatment accessibility, health equity

Introduction

More than 40 million Americans struggled with substance use disorders (SUD) in 2020 (1), many of whom are statistically likely to be pregnant or parenting (2, 3). It is difficult to estimate the national prevalence of SUD among pregnant and parenting people (e.g., due to the illegal nature of some substance use and lack of coordinated tracking across treatment facilities), but the prevalence of SUD among this group seems to be increasing (4). It has been estimated that 1 in 8 children live with a parent with a SUD (3).

The efficacy of evidence-based therapeutic interventions for SUD has now been established, with benefits across individuals, families, and society [e.g., (5, 6)]. Yet, only 1 in 5 people with SUD report receiving the treatment they need. Stigma has been named as a barrier to receiving care (1). The National Institute on Drug Abuse (NIDA) has identified stigma reduction as a major priority, emphasizing that stigma inhibits the implementation and adoption of effective treatments and harm-reduction approaches [e.g., medications for opioid use disorder and other addictions, syringe service programs, and fentanyl testing strips to avoid unintentional fentanyl exposure; (7)]. Social, self, and structural stigma toward individuals who use substances, which is notably higher than stigma toward those with mental illness broadly (8), is an important driver of low uptake of and adherence to these programs. This may be especially true for pregnant and parenting people with SUD who may experience greater stigma based on their pregnancy and parenting status (9). Despite growing knowledge of the genetic and social determinants of SUD, stigma toward pregnant and parenting people who use substances remains a barrier to accessing care and a significant public health concern.

There is a need to promote stigma reduction which may also reduce substance-related harm to parents and their children. While stigma exists at many levels of society, this article explores opportunities for the research community to mitigate substance-related stigma toward pregnant and parenting people through research dissemination of scholarly and non-scholarly products. These research products include journal articles, conference presentations, and community-facing information on findings. How researchers articulate and contextualize their research findings [e.g., through the rhetoric of maternal unfitness; (10)] can have consequences for intervention uptake, public perception, policy, and the way practitioners perceive, communicate, and treat pregnant and parenting people with SUD. Researchers can examine the existence of stigma within their work as part of a larger effort to alleviate the adverse effects of both stigma itself and the impacts of stigma on accessing health services.

We present strategies within a unifying framework to reduce stigmatization of pregnant and parenting individuals who use substances in the dissemination of research findings. The strategies we propose include: (1) address researcher stereotypes, prejudice, and misconceptions about pregnant and parenting people with SUD; (2) engage in interdisciplinary and transdisciplinary collaborations that engage with researchers who have lived experience in substance use; (3) use community-based approaches and engage community partners, (4) address stigmatizing language in science communication; (5) provide contextualizing information about the social and environmental factors that influence substance use among pregnant and parenting people; and (6) advocate for stigma-reducing policies in research articles and other scholarly products.

Impacts of social, self, and structural stigma surrounding substance use disorder on pregnant and parenting people

Despite the prevalence of pregnant and parenting people with SUD, only about 9% of those with SUD receive any kind of treatment (11). While these treatment rates are driven by multiple structural factors (e.g., limited availability of treatment centers, inability to access or afford care, and limited screening for SUD in medical visits), fear of shame and stigmatization in seeking care remains a key determinant of treatment engagement (12–14). Indeed, stigma has been proposed as a key barrier to treatment utilization for those with SUD (1)–and SUD is the most globally stigmatized health condition according to the World Health Organization (15). Researchers first need to understand the impact of stigma on this population.

Stigma is embedded at multiple layers of social interaction. Pregnant and parenting people who use substances may experience compounding social, structural, and self- stigmatization. Social stereotypes manifest behaviorally (e.g., by social distancing or discrimination) and, ultimately, hinder care delivery and undermine treatment access (16). Stigma at every level increases distress, social isolation, and diminished access to resources (17). Stigma also influences the progression from substance use to the development of a SUD, undermines SUD treatment efforts, and drives health inequities across the life course (18). Stigmatization of opioid use, for instance, has hindered the national response to the opioid crisis in the United States by reducing public support for beneficial programs, such as the uptake of effective harm reduction strategies and evidence-based treatment [e.g., medication for opioid use disorder; (16)].

Social stigma arises from stereotypes about people who use substances in general, including harmful narratives that people who use substances are dangerous or purposefully choose not to abide by moral societal standards. When health professionals endorse stereotype perceptions (e.g., assigning poor motivation to patients) and display diminished empathy, this impacts patient empowerment, quality of care, and the type of treatment that parents with SUD receive (8, 19). Disregarding patient autonomy and engaging in nonbeneficent care policies occurs disproportionately among care providers when treating people who use substances (16). The suboptimal medical care that results from stigma also occurs with respect to children of parents who use substances, including when medical conditions are assumed to be connected to substance exposure rather than their root cause (19–23). Ultimately, stigma impacts appropriate healthcare provision via barriers to health-seeking behavior, engagement in structures of care, and treatment adherence (24). Further, there are racial disparities in access to treatment for SUD (25), emphasizing that pregnant and parenting people who use substances and who have a minoritized racial identity are at risk of racial discrimination and greater stigmatization. Degree of social stigma can vary based on substance used. This form of social stigma is more often related to racialized narratives than to pharmacological impacts of the substances themselves (26). Indeed, more severe substance-specific social stereotypes have been weaponized to attack the parental fitness of minoritized groups (27). Conversely, substances commonly used by White, middle class individuals (e.g., alcohol and cannabis) tend to have less severe societal stigma (28). As such, it is important to consider racialized narratives that underly individual ideologies about the impacts of use.

Stereotypes about pregnant and parenting people with SUD, specifically, are often related to the potential of (1) prenatal substance use to cause fetal harm and (2) parental substance use to cause harm to the child. When examining these potential risks, social narratives commonly link substance use with "maternal unfitness" and focus on parental deficits, particularly when parents are compared to hegemonic ideals of parenthood (29). While it is critical to prevent and address potential harms associated with substance use during

pregnancy, the scientific evidence of actual meaningful consequences of exposure does not support the extent to which SUD has been linked to the unfitness of the birthing person to parent (10, 30). Instead, the narrative of parental unfitness undermines the importance of the parent -baby bond and often leads to depriving both mother and baby of the benefit of embeddedness in a supportive environment (30).

Focusing on parental deficits implies that parents who struggle with substance use are wholly unable to provide adequate nurturing to their children (31), despite the evidence of treatment and harm reduction approaches demonstrating that there are ways to use substances and still have strong parenting skills. For instance, our Center on Parenting and Opioids provides parenting resources to support parents to reduce substance use if that is their goal, reduce potential harm to self or child, and prepare for safe and successful parenting [e.g., obtaining additional supportive care when planning to use, not sleeping in the same bed with children, avoiding putting children around water, and keeping substances in medication boxes and away from children's access; (32)]. This and other treatment and harm reduction approaches (e.g., programs like HomeSafe in New Jersey) prioritize meeting the primary needs of the whole family by providing wrap-around services rather than penalizing the parent for use of substances (33).

Pregnant and parenting people with SUD are also vulnerable to *structural stigma*, wherein social stigma becomes embedded in cultural norms, laws, and the policies and procedures of institutions, restricting their rights and opportunities (16, 34). For instance, drug use in pregnancy is codified as child abuse and results in parenting individuals with a record of child abuse. Structural stigma results in limited access to housing, work opportunities, and medical and behavioral treatment (35). The narrative of "maternal unfitness" has led to government interventions and punitive actions against pregnant people, such as arrest, detention, loss of parental custody, or "lock-in" programs, in which individuals are restricted to only obtaining substances from a single pharmacy (10, 36, 37). Though designed to protect fetal health, these responses fail to consider scientific evidence related to individual values and motivations, successful treatment of SUD, and structural factors that undermine treatment utilization for both SUD and obstetrical care (10). In fact, punitive responses can exacerbate the issue, including predicting increased likelihood of infant Neonatal Abstinence Syndrome [NAS; (38, 39)].

Punitive policies are centralized around criminalization, leading to high rates of prosecution and incarceration, family separation (40–42), and fewer resources to support those who are affected by substance use [e.g., restrictions on treatment, limited access to overdose prevention sites, and fewer social services generally; (43)]. Punitive approaches further increase the likelihood that pregnant people (21), will avoid accessing healthcare, ultimately widening health inequities (44–46). The impact of stigma on healthcare utilization may be further compounded for parents facing housing instability or houselessness, who often do not seek out supportive services for fear of being separated from their children.

Stigma may impede the advancement of evidence-based healthcare delivery policies (8) and policies oriented toward public health, which are designed to support individuals through expanded services for prevention and treatment (37). Public health-oriented policies, such as the expansion of Medicaid insurance to cover prescription opioid treatment or laws that ensure that those seeking help for overdose are protected from criminal charges, aim to address substance use without inhibiting healthcare access (37). Unlike punitive approaches, public health approaches are grounded in the understanding of SUD as a chronic, but treatable, condition. In fact, many people successfully manage SUD (47) and there are many examples of pregnant and parenting people with SUD that demonstrate hope, resilience, and restoration (16).

Self-stigma occurs when pregnant and parenting individuals internalize negative societal beliefs and sentiments (48). Internalized narratives become predictive as individuals with SUD anticipate stigmatizing and judgmental treatment when interacting with providers and healthcare systems; ultimately leading to poorer health outcomes (16, 49) and retention and follow-up care challenges (50). Impacts of self-stigma on psychological well-being, self-efficacy and resultant treatment outcomes for those with substance use disorders are well-documented (51–54). The downstream mental health consequences of self-stigma may itself be a determinant for continued substance use. For instance, Khantzian's (55) *Self-medication Hypothesis* posits the misuse of substances as a self-regulation strategy to manage difficult life experiences, including stigma-related social anxiety and experiences of racial discrimination (38, 56, 57). Interventions that target experiences internalized stigma such as Acceptance and Commitment Therapy, are effective for reducing substance use and increasing treatment attendance (58, 59).

Overall, stigma harms pregnant and parenting individuals with SUD and their children by preventing access to necessary and vital services, contributing to internalized social devaluation, psychological distress, and underutilization of treatment (34, 48). These psychosocial and economic impacts further perpetuate challenges to parenting, impacting the families and children of parents with SUD. Critically, choices made within the research process such as language used to describe pregnant and parenting people who use substances and lack of inclusion of the role of stigma as a confounder to measured outcomes may perpetuate stigmatization and resulting discrimination. Examining opportunities to prevent the downstream impacts of research approaches that lead to stigma is an important step in creating supportive environments for pregnant and parenting people with SUD to ultimately improve health outcomes for this vulnerable population.

The role of research in shaping public perceptions, treatment utilization, and policy

Stigmatization that is created or upheld within research products may impact care experiences for pregnant and parenting individuals affected by SUD and their children by contributing to social, structural, and self-stigma. Stigma may arise in how research is conducted, shared, and interpreted. In many ways, effectively destigmatizing research starts even before the data are collected; it begins with working alongside and uplifting the voices of the individuals and communities under examination (60). Stigmatizing beliefs exist within research toward individuals who use substances generally, as described by Stull et al. (61), p. 2:

> 'Those of us who have conducted human research have noticed that beliefs about addiction are incorporated into every aspect of it–the framing of questions, the screening criteria for studies, the

> experimental manipulations used in human laboratory sessions, and the outcome measures used in clinical trials or assessment studies. Most of those beliefs are based on data and are defensible, but often they do not allow for the degree of heterogeneity that we know, from experience, is characteristic of addiction.'

Ultimately, there is a need for a "toolbox" of various strategies and evidence-based interventions that address the multiple levels at which stigma arises [e.g., (17, 62, 63)]. However, to provide timely guidance to researchers who are ready to share findings, the remainder of this paper will focus on strategies to reduce stigma toward pregnant and parenting people with SUD as it relates to the dissemination of research products.

Within dissemination, stigma may arise in how we portray our research, how it is shared, and how it is interpreted; impacting health and well-being experiences for pregnant and parenting individuals affected by substance use disorder. Stigma is a driving factor in the persistent barriers to the equitable and efficient translation of research into clinical practice, public health benefit, and policy change (64). There have been numerous calls for research to be increasingly patient-oriented (65, 66) and sensitive to the social impact of scientific research (67)–and for the creation of guidelines to support researchers in considering the way in which they frame SUD during publication (68). Stigmatizing pregnant and parenting individuals with SUD may prevent evidence-based practices in reaching implementation stages and later translation to community health policies and programs. To the extent that research products inform policy and institutional procedure, these products may inadvertently perpetuate structural stigma. Researchers may lend support to punitive approaches by failing to explore the potential for public health and harm reduction approaches to confer beneficial outcomes for pregnant and parenting people who use substances and their families.

Eliminating the use of stigmatizing narratives within the dissemination of research products is one step toward improving the ways society and care providers interact with pregnant and parenting people with SUD. The unconscious and insidious nature of stigma suggests the need for our active engagement to decrease substance-related stigma toward pregnant and parenting individuals in research dissemination. Using a framework to guide the research process increases impact (69). There are dozens of frameworks of research dissemination and implementation, with much of the guiding content focused on structural aspects of dissemination, such as research planning and measures selection (69). To our knowledge, there are no comprehensive frameworks to reduce stigma within research products related to SUD among pregnant and parenting individuals.

A framework of strategies to reduce stigma in the dissemination of research findings

We present the following strategies for guiding efforts to reduce stigma within research dissemination for pregnant and parenting people affected by SUD. We draw from related frameworks [e.g., The Health Stigma and Discrimination Framework; (26)], which articulate the process of stigmatization in the context of health broadly, to frame stigma-reduction strategies within research dissemination to reduce harm caused to pregnant and parenting individuals with SUD. We suggest how key components of these frameworks might be integrated into the dissemination of research products for those conducting research involving pregnant and parenting people with SUD. We provide a multi-level approach to consider the various levels that may perpetuate or address stigma (18). These strategies are organized by order of operations when approaching dissemination planning and procedures for research efforts (see Table 1).

Actionable recommendations

Strategy #1: address researcher stereotypes, prejudice, and misconceptions about pregnant and parenting people with SUD

Despite positive intentions within the research community, normative judgments that exist at both conscious and unconscious levels are reflected in scientific endeavors and perpetuate stigma (70). Specifically, generalized assumptions that people with SUD are incapable of providing a supportive caregiving environment are reflected in academic language and are used to justify harmful and unwarranted child welfare reporting practices. Stigmatizing attitudes are known to be most prevalent among those without knowledge of or experience with a stigmatized condition [e.g., (71)]. Without direct experience, for instance, researchers might not have had the opportunity to observe pregnant and parenting people who use substances acting as competent parents or recovering from SUD. Narratives that over-emphasize negative attributes and life circumstances can increase stigmatization (72). Effective stigma reduction strategies, such as providing education on stigma reduction or social contact interventions that focus on sharing experiences or stories of competent parenting or recovery among pregnant and parenting people with SUD, can be incorporated into research dissemination practices. For example, including a narrative account in tandem with quantitative research findings. Additionally, the enhanced stigmatization that is accompanied by the use of certain substances such as heroin (73) and methamphetamine (74) or the modality of use such as injection (75), necessitates the inclusion of parents with specific lived and living expertise to provide their accounts of parenting, particularly as it relates to the pain of removal, the hope of family cohesion, and the successful navigation of parenting when adequate social supports exist.

Evidence of the detrimental impacts of the negative attitudes upheld by health professionals [i.e., diminished communication and hindering the therapeutic alliance for clinical interventions; (76)]

TABLE 1 Strategies for reducing stigma toward pregnant and parenting people with SUD within research dissemination.

1. Address researcher stereotypes, prejudice, and misconceptions about pregnant and parenting people with SUD
2. Engage in interdisciplinary and transdisciplinary collaborations–emphasizing engagement with researchers with lived experience
3. Use community-based approaches and engage community partners
4. Address stigmatizing language in science communication
5. Provide contextualizing information about the social and environmental factors that influence substance use among pregnant and parenting people
6. Advocate for stigma-reducing policies in research articles and other scholarly products

suggests that negative attitudes among researchers may have similar negative consequences. Researchers can examine personal biases toward pregnant and parenting people who use substances to mitigate potential harm resulting from research products. Beyond the potential to create negative experiences and outcomes of study participants, impact study adherence, and inhibit researcher awareness about relevant study events, diminished communication can negatively influence our theoretical approaches and interpretation of findings. Like 'diagnostic overshadowing,' wherein physical illness symptoms are misattributed to mental illness and result in underdiagnosis (77), our theoretical framings may incorrectly disregard important participant comorbidities or inaccurately assume they are a feature of substance use. The perceptions we hold about the controllability and culpability of having SUD, known as attributional beliefs, may impact the way we frame SUD in our research products. For instance, attributional beliefs may lead to reporting about SUD using a framework based on individualism and personal responsibility (e.g., narratives of "maternal unfitness") rather than discussing upstream and social causes, which can change social perceptions and ultimately reduce motivation for social and interpersonal responsibility-taking behaviors (78). Meaningful interaction with individuals who have had the direct experience of substance use while pregnant and parenting may reduce biases by reducing anxiety related to those interactions, increasing knowledge about the lived experience of those individuals, and enhancing empathy [e.g., Pettigrew and Tropp's contact hypothesis; (79)].

Models that recognize the physiological and psychosocial drivers of SUD (e.g., disease models and biopsychosocial models) may minimize the moralization of substance use and therefore reduce stigmatizing beliefs toward pregnant and parenting people who use substances. NIDA promotes the characterization of SUD as a "chronic relapsing brain disorder" that "powerfully compromises executive function circuits that mediate self-control and decision-making" as a method of stigma reduction toward those with SUDs (7). Compared to other models that have a focus on will power or personal characteristics as a driving element of SUD, recognizing the complex biopsychosocial drivers of SUD is both more accurate and more likely to prevent stigma. For example, the disease model asserts that a pregnant person who uses substances during pregnancy can be seen as someone suffering from a chronic disorder, rather than as someone who is choosing to actively harm their developing fetus. However, disease models may also be vulnerable to the process of moralization (80), and require reflection on how assertions of moral responsibility within our theoretical approaches may inform stigma. Biopsychosocial models consider psychological attributes, individual skills, and social and environmental context, which may increase understanding about the internal mechanisms of use within the individual. The integration of these models is important for providing holistic care for pregnant and parenting people with SUD. However, neither of these models fully address social and structural determinants of health, which are key drivers of parent substance use (81, 82).

To the extent that stigma occurs at the unconscious level, it is crucial to proactively support stigma reduction efforts by increasing awareness of social, self, and structural stigma. Specifically, we propose developing a clear understanding of stigma and its effects, becoming aware of and responsive to self-stigma among pregnant and parenting people with SUD [as recommended by Crandall and Holder; (83)], and using continuing education, self-evaluation tools, and professional training to reduce professional stigma. As awareness grows of the impact of stigma on individuals with SUD accessing care, the National Institutes of Health (NIH) has recently released various funding opportunities for research on trainings and tools designed to reduce stigma around SUD. Stigma is a fundamental cause of health inequities across the life course (18), and NIH continues to provide information and resources for stigma reduction in research [e.g., (62)].

Researchers can commit to participation in training opportunities designed to expose our normative judgments and to ensure that we have meaningful contact with the communities that are the focus of our research. For instance, the Mental Health First Aid training program, which focuses on mental health and substance use issues, has been shown to enhance knowledge and reduce stigmatizing perceptions (84). A growing number of training programs are available, such as those offered by Zero Block Society (85) and Prevention Technology Transfer Centers (86), as well as the perinatal harm reduction toolkit [e.g., (87, 88)]. More such training programs are needed. The NIH offers training to reduce stigma toward people who use opioids for primary care clinicians through their HEAL Initiative (88), though we are not aware of training targeted for researchers. The Center for Parenting and Opioids (CPO) has offered several trainings for researchers, including one on community-based research focused on partnerships between researchers and harm reduction frontline workers in Vancouver, British Columbia (the recording is publicly available[1]).

Contact-based training and education programs are effective for addressing stigma (89), including among medical students and professionals (34). Engagement with people who have the lived experience of substance use while pregnant and/or parenting during stigma reduction trainings may enhance the effectiveness of stigma reduction training (90). Articles that highlight the lived experiences of pregnant and parenting people with SUD can be included in stigma reduction training, such as from the perinatal harm reduction coalition. At the time of this writing, the Journal of Substance Use and Addiction Treatment offers regular "lived experience" publications designed to "honor stories of addiction and recovery, mitigate stigma through a humanized portrayal of persons, families and caregivers affected by SUD, raise issues of social justice and inequity, explore the dynamics of patient-clinician relationships, and foster compassionate engagement with people with SUD" (91) and has published qualitative reports of the lived experience of pregnant and parenting people with SUD (92).

Strategy #2: engage in interdisciplinary and transdisciplinary collaborations

A variety of perspectives, frameworks, and lived experiences are needed to identify and address stigmatizing elements in research dissemination. From the perspective of expanding frameworks and approaches among researchers themselves, interdisciplinary and transdisciplinary approaches have the potential to shed light on the unrealized elements of our research that may otherwise introduce stigmatizing frameworks. The lack of careful examination of information being reviewed and communication issues across fields (93) demands an increase in ongoing collaboration with individuals

1 https://www.cpo.uoregon.edu

from different fields of study. Transdisciplinary collaborations may enhance understanding about the role of stigma in treatment outcomes and address the complex, multifaceted social phenomenon of stigma within research products [e.g., (94, 95)]. NIDA has funded several Transdisciplinary Prevention Research Centers (TPRCs) to "foster innovative translation of theories across disciplines" and "overcome the barriers inherent in integrating cross-disciplinary concepts, methods, and findings" (96).

Interdisciplinary and transdisciplinary collaborations may represent multiple benefits. For instance, they may enhance understanding of multiple streams of evidence and generate more practical and robust knowledge about the life course impacts of both fetal drug exposure and SUD-related stigma. Research collaborations also represent an opportunity for research teams to mutually inform one another's approaches to stigma reduction. This would further promote clear and adaptable stigma reduction strategies that can be applied to many fields. Finally, collaborative approaches increase the likelihood of engaging with researchers with SUD in the context of pregnancy and parenting, who bring an informed perspective and awareness to the research process (61). While individual discretion related to self-disclosure of stigmatized identities among researchers with SUD should take precedence, doing so may further promote empowerment and reduce self-stigma (89), especially when safe spaces to do so exist.

Strategy #3: use community-based approaches and engage community partners

Research initiatives are too often out of touch with the communities they seek to study or serve (97). For instance, researchers may assume that parents who use substances have access to certain kinds of technology or fail to identify historical and cultural elements that inform their degree of engagement. We may not recognize misalignments between the values driving proposed studies and those of pregnant and parenting individuals with SUD (98), leading to oversights that may perpetuate stigma. Meta-analyzes and systematic reviews have demonstrated that community-based, patient-centered approaches can improve utilization and treatment outcomes for evidence-based substance use treatments (99, 100).

Community-based practices, such as engaging community advisory boards and digesting information from community surveys prior to introducing community health services, represent an ethical standard of inclusivity and have been found to reduce stigma and enhance care seeking (101). Community-based participatory research (CBPR) approaches can guide researchers in this process [e.g., having a prevention focus, being population-centered and collaborative, taking a multi-disciplinary approach, building on community strengths and resources, attending to social inequalities, taking an ecological perspective, and prioritizing mutual benefits for all partners; (102, 103)]. Researchers can increase community involvement by identifying relevant partner organizations (e.g., non-profits, community health centers, and peer organizations), planning research activities that meaningfully engage pregnant and parenting people with SUD in the research dissemination process (e.g., public presentation of study findings), ensuring that findings are communicated in understandable and usable ways (Patient-Centered Outcomes Research Institute; PCORI), and providing interventionists and practitioners structures for soliciting and communicating feedback passed along to them by participants and community partners about research products. Community partners should represent the specific population within the research, including subpopulations of pregnant and parenting people with SUD, who may differ in factors such as substances used or features of their SUD–as well as substance-specific stigmatization. For instance, not convening individuals with alcohol use disorder to provide insight into stigmatizing experiences among those with opioid use disorder who are injecting substances. This is even more relevant considering that those who use certain substances may themselves stigmatize those who use other substances. Pregnant and parenting people that use highly stigmatized substances are silenced by the systems they engage with. Researchers must understand how to create space, actively listen, and validate the experiences of these vulnerable groups. Including a member of the research team with experience facilitating groups, especially a researcher with lived experience, may improve the experiences of participants. Highly studied populations frequently emphasize the importance of researchers committing to real and meaningful benefit to study participants, including a plan for actively advocating for change based on research findings [e.g., (60)]. Community-based practices encourage the creation of valuable materials (i.e., related to childcare, lactation spaces, or parenting practices) or novel resources for participants (e.g., affinity groups for those who have experienced loss or child removal).

The Patient-Centered Outcomes Research Institute[2] provides grant funding and an online repository of engagement-related tools and resources including "stakeholder engagement plans," to enhance effectiveness and likelihood of translation and dissemination of research. In addition to informing our research on the whole, involvement of pregnant and parenting people with SUD ensures relevancy of the research to this community and can help bring attention to potentially stigmatizing aspects of the research. Thong et al. (104) recommends researchers receive training on building rapport and engaging more deeply with prospective participants by involving participants' families or significant others and taking time to discuss important elements of the research process. Others point to working with peer outreach workers and organizations to help build trust and participation (105, 106).

In addition to connecting directly with pregnant and parenting people who use substances, researchers can partner with Community-Based Organizations (CBOs) who engage with this group (107). CBOs are often familiar with community strengths, needs, and challenges. PCORI's "Stakeholders' Substance Use Research and Treatment Information Exchange" (SSURTIE) supports efforts to design and develop infrastructure to promote increased collaboration among researchers who focus on SUD and the community partners who are affected by the disorder or who provide treatment (108). Guidelines frequently emphasize the importance of developing trusting relationships with community partners and allowing their input to define the evidence collected, critically reflecting on and dismantling power structures, exploring potential adaptations relevant to the community being considered, and engaging in critical evaluation of

2 https://www.pcori.org/

how scientific frameworks and approaches may contribute to barriers by perpetuating stigma.

Strategy #4: address stigmatizing language in science communication

Stigma toward substance use and SUD has become embedded in language itself, in part due to political rhetoric aimed at reducing substance use (109, 110). For instance, the terms "addict" and "junkie" contribute to stigma among people with SUD (111). Calls have been made for scholars to "carefully and intentionally consider the language used to describe... drug use and disorders, the individuals affected by these conditions, and their related behaviors, comorbidities, treatment, and recovery" within research products (68), pp. 2. Indeed, language influences public perceptions regarding the cause and modifiability of substance use, as well as personal perceptions related to self-efficacy among those impacted (68). As language is a known driver of social and individual perceptions of SUD, examining our language choices within research products related to pregnant and parenting individuals may reduce stigma toward this population. Synthesizing these recommendations, we propose the following strategies: use language that (1) Respects the worth and dignity of all persons ("person-first language"), (2) Focuses on the medical nature of SUD and treatment, (3) Promotes the recovery process, and (4) Avoids perpetuating negative stereotypes and biases with slang and idioms (68).

"Person-first language" emphasizes the person over their condition when referring to individuals affected by SUD, for example, "people with OUD" instead of "opioid users." The mere use of the term 'substance abuser' versus 'having a substance use disorder,' leads to beliefs that individuals with SUD engage in willful misconduct, pose a greater threat to society, and are more deserving of punishment (112). Nonetheless, person-first language remains uncommon in the research literature on substance use (113). The research community can adopt the use of person-first language (rather than disease-first terminology) by using terms such as 'person with a SUD', 'person who uses drugs', or 'parent who misuses opioids' instead of 'substance abuser' or 'substance using' (19, 112). The Drug Policy Alliance recommends the use of the terms "person with substance use disorder or SUD" and "person who uses/injects drugs (PWUD/PWID)" (114). Gender specific language is important in some contexts, such as when examining differential outcomes or tailored treatment approaches. Researchers can use gender inclusive language when reporting about gender non-specific research related to pregnant and parenting people, who can be of all genders. For instance, the use of gender inclusive terms such as "pregnancy," "pregnant people," "during pregnancy," "birth," and "birthing parent." Researchers can also practice inclusivity through conducting research with pregnant and parenting people who are not cis-gendered. In general, there is little information about the parenting experiences of men with SUD (115, 116) and far less (if anything) about people who are not cis-gender (117).

Regarding children who have been exposed to opioids *in utero* and/or have become physiologically dependent on substances they were exposed to *in utero*, the National Perinatal Association recommends the phrase child with "prenatal substance exposure" or "physiological dependance," rather than with the term "addict" or "addicted baby," (118). They highlight the importance of underscoring that withdrawal is a temporary and treatable condition and that their drug exposure does is not fundamentally deterministic of their long-term outcomes overall (118). This value-neutral language focuses on the effects of the use of substances, rather than the consequences, when referring to the individual.

The Associated Press Stylebook (119) provides journalistic guidelines for language use within articles related to mental illness. NIH has developed a resource that outlines various considerations when reporting scientific findings and has published a *Checklist for Communicating Science and Health Research to the Public* (120), which includes a guideline for researchers to "convey information in a respectful tone that [does not] stigmatize or assign blame to individuals or groups [affected by the disorder]" (121). The Recovery Research Institute has created the "addictionary" for the purpose of creating a unified language to destigmatize addiction (122). Several institutes, including NIDA and the National Institute on Alcohol Abuse and Alcoholism (NIAAA), have their own guidelines for person-first language. Community advisory board members can also be consulted about the terms they use when describing themselves, and the terms they prefer never to be used (123).

Strategy #5: provide contextualizing information about the social and environmental factors that influence substance use among pregnant and parenting people

SUD, pregnancy, and parenting do not occur independently of social, environmental, and genetic factors, which have all been demonstrated as determinants of substance use initiation (124). Social and structural determinants of substance use, such as socioeconomic status, disparities in healthcare delivery, discrimination, racism, and social exclusion, have been well-documented (25, 125, 126). These structural factors, along with fear of related stigma, additionally drive treatment engagement (14). Without critically examining their frameworks and analytical approaches, researchers may unintentionally over-emphasize the role of parental substance use in public health issues, neglect to consider how the framing of study results will be perceived by society, or engage in "stigma by omission" (i.e., failing to acknowledge the important role of social and structural factors in SUD). Researchers can work to avoid the tendency to discount social contextual factors that influence child development and behavioral changes, which are more robust predictors of these outcomes than substance exposure alone (127). As misconceptions about the nature and strength of the relationship between exposure and developmental outcomes (see 10) may lead to researcher prejudice, addressing these misconceptions is needed. Despite extensive evidence of contextual and genetic influences on substance use, theoretical frameworks presented in scientific communications often do not acknowledge the role of factors outside individuals. This kind of de-contextualized communication may overemphasize the role of individual characteristics, such as lack of motivation or interest on the part of the individual, as the primary drivers of substance use and treatment non-initiation. For instance, many scientific frameworks for understanding substance use exclusively focus on internal psychological and behavioral mechanisms such as self-regulatory processes and habit extinction (128, 129). While individual-level factors are certainly related to substance use disorder trajectories, a failure to nest individual factors within the broader context may influence self-stigma related to personal ability to recover (130) and stigmatization within treatment systems of care (8). This lack of context may even translate to our statistical approaches. As noted by Terplan (131), p. 1729:

> 'Categories such as race, gender, pregnancy, poverty, immigration status, sexual orientation, and medical comorbidities interact in an integrative (not additive or multiplicative) fashion. Logistic regression, even when augmented by sensitivity analyses, therefore executes a leveling effect on the data and, with each turn of the model, whittles away the richness, nuance, and suffering that is the human experience.'

In this way, guiding theories and patterns of data interpretation often "fail in scope to represent the many experiences of addiction" (61), p. 2.

Researchers can reduce stigma toward pregnant and parenting people who use substances by ensuring accurate representation of existing research and considering whether previous research has appropriately accounted for contextual factors. This includes exercising caution not to overstate findings. Researchers can vet research that is peer-reviewed and evidence-based, such as high-quality observational studies that adjust for potential confounding, randomized controlled trials, or meta-analysis. Adjusting for confounding (e.g., of socioeconomic and sociocultural variables) is especially important regarding reporting of biological effects on *in-utero* exposure to substances and when studying parenting behaviors, which are often sensationalized.

Contextual theoretical frameworks such as Bronfenbrenner's Social Ecological Framework (132) or Engel's Biopsychosocial Model (133) outline the multiply determined nature of SUD. Contextual frameworks incorporate key drivers in the development and onset of SUD, such as social isolation or social rejection [see (116, 127) for examples]. By contextualizing substance use within research frameworks, researchers can frame the biological, social, and structural drivers of substance use. These frameworks may both address the determinants driving substance use more effectively and shift public perceptions regarding those who are affected by SUD. This can be done even if the study did not take a contextual approach during the design phase, through providing this context in the introductory and discussion sections of the paper.

Research related to the impact of substance use on pregnant and parenting people and their families often focuses heavily on the outcomes related to children [e.g., (134)], rather than providing a balanced lens that also considers the parents' wellbeing and the functioning of the family. This has led, for instance, to a research base that minimizes the harmful effects of the removal of children from their families. Family preservation approaches emphasize the responsibility of society to minimize the destructive potential impact of the child welfare system (135). Further, research products that overly focus on the child may inadvertently generate additional stigma toward children whose parents use substances. Indeed, people who experienced parental substance use report experiences of stigma and social exclusion (136). Research efforts aimed at supporting families in the context of substance use can consider how the parent might be best supported while they are with their child(ren).

Strategy #6: advocate for stigma-reducing policies in research articles and other scholarly products

Research plays a role in creating and amending policy. This occurs directly through channels by which research is communicated to policymakers and indirectly through influencing public interpretation of research theories and results (137). For instance, research informs evidence-based policies that have downstream impacts on treatment of parental SUD, including within the child welfare system (138). Indeed, research on the importance of parent–child relationships has encouraged policies that reunite children who have been removed from their home as a result of substance use, as opposed to previous policy that promoted children remaining with temporary caregivers (138). Careful evaluation of how we are portraying the implications of our findings may prevent unintended contribution to harmful policy.

Researchers can discuss our findings and their implications within the broader context of social policy in ways that minimize stigma. Grantmaking bodies are increasingly inviting researchers to submit "impact statements," which are intended to demonstrate the potential benefit research might have in the world. Impact statements that (1) plainly discuss how findings relate to family policy and (2) clearly address how findings could be misinterpreted to promote stigmatizing family policy are critical for stigma reduction. Impact statements are an opportunity to clearly address what findings do and do not imply for public policy. For instance, researchers who evaluate the effects of substances on parenting practices can emphasize that their individual findings do not imply support for unethical child removal practices when applicable. Researchers can also make connections from their findings to policies that reduce harm for parents with SUD and their children (i.e., reunification practices and social support services).

Researchers can also proactively advocate for the development of frameworks and guidelines for stigma reduction when conducting research from influential regulatory and grantmaking bodies. Locally, researchers can work with their Institutional Review Boards (IRBs) to advocate for frameworks and guidelines for stigma reduction when conducting studies. IRBs can be encouraged to develop guidelines related to non-stigmatizing terminology and to support researchers to meaningfully consider practices to reduce stigma resulting from research participation for pregnant and parenting individuals who use substances. Nationally, laws related to stigma-reduction practices would afford dissemination guidelines a judicial basis and ensure that ethical review boards work to uphold these ethical standards (139). Researchers can also directly engage in dissemination efforts that connect our research to policies which impact pregnant and parenting individuals with SUD and their families. For instance, becoming aware of gaps in policy can provide insight into where more research is needed. The Research-to-Policy Collaboration (140) is one organization that connects researchers to relevant needs in policymaking. While research can directly inform policy, we can actively use our leverage as researchers to inform public opinion, including through op-ed papers. Publishing expert opinion in public news draws the attention of policy makers and promotes social pressure that can aid in the development or amendment of policy.

See Table 2 for a summary of proposed strategies and actionable recommendations.

A case study: stigma-reduction efforts at the center on parenting and opioids

While implementing these practices is a long-term goal that is not without barriers, we aim to support researchers in taking steps toward minimizing substance-related stigma. The authors of this publication are colleagues at The Center on Parenting and Opioids (CPO), where we are implementing steps to align with the strategies outlined in this paper. The CPO is funded by NIDA and is jointly housed at the University of Oregon and Oregon Health & Science University. We hope our work at the CPO provides an example of taking meaningful steps toward

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TABLE 2 Actionable steps to reduce stigma within research dissemination.

Strategy	Key message	Actions researchers can take
1. Address Researcher Stereotypes, Prejudice, and Misconceptions about Pregnant and Parenting People with SUD	Judgments, biases, and misconceptions on the researcher's part may influence public and self-stigma, addressing these is critical.	• Participate in trainings to expose normative judgments and engage with pregnant and parenting people who experience SUD (e.g., Mental Health First Aid, Zero Block Society, or Prevention Technology Transfer Centers)
		• Read The Journal of Substance Use and Addiction Treatment "lived experience" publication series and harm reduction toolkits (e.g., from the Perinatal Harm Reduction Coalition).
2. Engage in interdisciplinary and transdisciplinary collaborations	Transdisciplinary collaborations help us to understand and address stigma, which is a complex, multilevel social phenomenon. Researchers with lived experience exist and have valuable insights and can provide valuable insight into how to reduce stigma in research products for dissemination. They can also act as brokers between other researchers and the community.	• Invite researchers from relevant fields to support the framing within research products.
		• Engage with researchers who are abstinent/in recovery or currently use drugs to consult on the language used in scholarly products.
		• Create collaborative spaces for researchers with and without lived experience to engage with community partners on language and dissemination practices.
		• Follow work from NIDA's Transdisciplinary Prevention Research Centers (TPRCs)
3. Use community-based approaches and engage community partners	Research approaches that actively engage the community partners most involved with and impacted by the conditions being researched (e.g., community-based research models) may successfully reduce stigma.	• Conduct community advisory boards.
		• Access PCORI's resources (e.g., "stakeholder engagement plans").
4. Address stigmatizing language in science communication	Community-informed resources for de-stigmatized terms (e.g., person-first language) are available and constantly evolving.	• Avoid the use of slang and idioms.
		• Use current resources, such as NIDA's "words matter" resource, "the addictionary," and NIH's recommendations for reducing alcohol-related stigma that inform the use of de-stigmatized terminology.
		• Focus on the medical nature of SUD and treatment.
		• Use "recovery-promoting" language.
5. Provide contextualizing information about the social and environmental factors that influence substance use among pregnant and parenting people	Theoretical frameworks presented by the researchers shape self and public perception - utilizing contextual frameworks that recognize the multiply determined nature of substance use may minimize stigma.	• Utilize contextual theoretical frameworks that acknowledge biological, social, political, and environmental determinants of SUD within research products.
		• Ensure accurate representation of existing research
		• Avoid overly focusing on the child
6. Advocate for stigma-reducing policies in research articles and other scholarly products	Policies and guidelines reinforce scientific procedures and communication strategies, which can be leveraged to reduce stigma.	• Clearly state how public policy is affecting your sample in academic papers.
		• Write to funding and publishing bodies to advocate for the development of stigma-reducing policies and guidelines.
		• Learn about the research-to-policy collaboration

bridging the gap between rigorous science and community impact. From professional workshops to a Knowledge Dissemination working group, the CPO's initiatives seek to not only challenge researchers to engage reflexively with their research, but to also guide science communicators toward sharing research outcomes and policy recommendations in a way that reduces stigma and expands accessibility to information.

One such initiative is the composition of research briefs that synthesize key findings from current CPO-affiliated studies, with a focus on highlighting the practical utility of science. To actively work toward reducing the stigmatizing language that all too often surrounds research on substance use–particularly regarding pregnant and parenting people who use substances–the CPO has also generated a *Destigmatizing Research Dissemination Checklist* specifically intended for those writing and reviewing the research briefs. The *Destigmatizing Research Dissemination Checklist* includes items such as "building on community strengths" and "highlighting the utility of research," with practical tips like (1) writing with a collective tone to avoid othering the communities we seek to positively impact and (2) using destigmatizing and person-first language. While attending to language and terminology is just one step toward reducing stigma in science (see Table 2), the CPO's research briefs and Checklist represent an initiative designed to prioritize stigma reduction in research products. Our aim is for these institutional changes to impact social, self, and structural stigma.

Discussion

The goal of this set of strategies is to empower researchers to destigmatize their research products. We anticipate that by reducing stigma in research products, we will be able to reduce self-stigma, social stigma enacted by professionals who care for pregnant and parenting people with SUD, and structural stigma upheld by

organizational, local, state, and federal policies. However, there are limitations to our proposed strategies. First, we understand that it takes time and energy to engage with community partners. While we believe their investment and direction is well worth the additional expenditures, we understand that community-engaged research is a new skill that many researchers do not currently practice or have access to training opportunities to learn. We also understand that the academic cycle does not currently well-incentivize community engagement, but incentivizes the quantity of scholarly products published in peer-reviewed journals and grants that bring institutional funding. Thus, destigmatizing research products also requires that the approaches outlined in our work are institutional priorities.

This paper explores opportunities to minimize stigma in the dissemination of research findings to relevant clinical, regulatory, and community audiences, with a specific focus on pregnant and parenting individuals with SUD. However, stigma reduction efforts are needed at all levels of the research process (e.g., planning, research conduct, and interpretation of findings). Examinations of stigma reduction practices across research phases is needed to produce research that accurately and substantively represents those individuals with SUD (141). Enacted stigma at every phase of research can create barriers to participation and preclude many people with SUD from feeling able or being able to participate in studies, ultimately limiting the generalizability of research findings. Additional work is needed to address participation barriers not discussed extensively here, including physical resource limitations [e.g., unstable housing, limited access to transportation, or lack of childcare; (111)], as well as related barriers, such as generalized mistrust of researchers, fear of legal repercussions, or duration and magnitude of the study (142).

The stigma reduction framework outlined here can be used to guide the examination of ways in which stigma has been perpetuated in prior research products. We also suggest that our proposed strategies may be modified to consider how to reduce stigmatization during other research processes.

We have argued that low participation in evidence-based substance misuse prevention and harm reduction programs among pregnant and parenting people who use substances is due in part to the role of stigma toward this group. We emphasize the detrimental impact of stigma at the level of the individual, society, and institution which includes undermining efforts to prevent and treat SUD and perpetuates health inequities. We examined the role of research in perpetuating stigma and its downstream effects and provided guidance based on available theory and evidence for practices to reduce stigma within our research products. These are: (1) address researcher stereotypes, prejudice, and misconceptions about pregnant and parenting people with SUD; (2) engage in interdisciplinary and transdisciplinary collaborations - emphasizing engagement with researchers with lived experience; (3) use community-based approaches and engage community partners, (4) address stigmatizing language in science communication; (5) provide context for research related to pregnant and parenting people with SUD; and (6) advocate for stigma-reducing policies in research articles and other scholarly products. By endeavoring to reduce stigma in our research dissemination practices, we may not only improve our theories, but also the degree to which our findings have real-world impact that minimize stigmatization and discrimination and ultimately transform health outcomes for families impacted by SUD.

Author contributions

ML, SM, KW-S, and CC contributed to conception of the paper. ML was the primary author of the manuscript. KW-S, SM, EB, and CC wrote sections of the manuscript. CC, ML, ETB, and MT provided edits and feedback to the draft. ML and CC revised the manuscript. All authors read and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Community-based counselling programme for pregnant women with alcohol problems in Cape Town, South Africa: a qualitative study of the views of pregnant women and healthcare professionals

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Introduction: South Africa lacks services to detect and address alcohol use during pregnancy, particularly outside of health-care facilities. This study aimed to explore pregnant women and healthcare providers' perceptions of the acceptability, feasibility and appeal of a community-based counselling programme for pregnant women with alcohol problems.

Methods: Twenty-eight in-depth interviews with pregnant women who drink, Community Health Workers (CHWs) and antenatal service providers were conducted. Transcribed interviews were analyzed thematically using a combined deductive and inductive approach.

Results: Women reported feeling uncomfortable seeking help for their alcohol use at antenatal clinics, limiting usefulness of current support services. All stakeholders perceived a community-based intervention to be acceptable and feasible as it could be integrated with other CHW-delivered services. Participants thought an intervention should facilitate early linkage to antenatal services and should include partners or family members. The feasibility of an intervention may depend on the relationship between CHWs and clinic-based antenatal staff, and their relationships with pregnant women. Clinic and community challenges to implementation were raised. Clinic-level challenges included shortage of space, staff capacity, high number of pregnant women, long waiting times, financial burden of having to travel to a clinic, lack of comfort and privacy and staff attitudes. Community-level challenges included crime, lack of privacy, lack of attention given competing interests in the home, fear due to abuse, and stigma and discrimination from other community members. Suggestions for overcoming these challenges were provided.

Conclusion: Findings provide essential information to facilitate the adaptation of a community-based alcohol counselling programme for greater acceptability, feasibility and cultural appropriateness for the South African context. Intensive training, supervision and support is required to ensure the programme is delivered as planned.

KEYWORDS

pregnant women, alcohol, counselling, community health workers (CHWs), South Africa

1. Background

Prenatal exposure to alcohol can cause pregnancy, neonatal and birth complications, including miscarriage, low birth weight and poor growth outcomes, stillbirth, and lifelong disorders including foetal alcohol spectrum disorders (FASD) (1–3). FASD is an umbrella term which describes several conditions associated with foetal alcohol exposure (foetal alcohol effects, partial foetal alcohol syndrome, alcohol-related birth defects and alcohol-related neurodevelopmental disorder) (4). South Africa (SA) is estimated to have the highest prevalence of FASD globally with 111 cases per 1,000 population (5); and the prevalence is particularly high (and rising) in the wine-growing region of the Western Cape of SA where estimated prevalence is 20–28% (6–9). Drinking amongst pregnant women is common, particularly in the impoverished townships of the Western Cape, where alcohol intake during pregnancy has become normalized (10). The prevalence of alcohol consumption in pregnancy, (including heavy episodic drinking) has ranged from 20–61% across various studies covering a range of measures of frequency and quantity (10–12) with approximately 20% of women who are pregnant testing positive for alcohol use by urinalysis (12).

Guidelines for the identification and management of substance use and substance use disorders in pregnancy have been developed by the WHO to provide evidence-based advice that can be applied within countries (13). Despite some efforts to address the high prevalence of FASD and the availability of guidelines for the prevention and management of FASD in SA (14), there is no national, coordinated, multisectoral effort or specific policies to address FASD (15, 16). Locally, services to detect alcohol use during pregnancy and to prevent alcohol-exposed pregnancies (AEPs) are largely absent outside of antenatal services offered through primary health care (PHC) clinics (17). Pregnant women who drink alcohol do not access these facility-based antenatal services until late in their pregnancies, with more than 75% of women accessing antenatal care for the first time during their second trimester and beyond (12, 18). Service planners in the Western Cape recognise that, to reach pregnant women at risk of having an alcohol exposed pregnancy for counselling, they need to move beyond only offering services in PHC clinics to include community-based services that reach women in their communities. This is especially important to facilitate earlier pregnancy recognition for women who have unplanned pregnancies, resulting in delayed access to antenatal services. Given shortages of health care professionals, these community-based antenatal services have been task-shared from nurses and midwives to trained community health workers (CHWs). South Africa has adopted task-sharing as a strategy for overcoming human resource shortages for health, as recommended by the WHO (19). CHWs form a bridge between communities and healthcare facilities (20). CHWs in the Western Cape are trained to provide a range of community-based health services that have historically focused on the prevention and management of infectious and non-communicable diseases (21), but have recently been extended to include early pregnancy and postnatal care (22). Whilst they undergo training in maternal and child health care, this training does not address how to recognise or address alcohol use amongst pregnant women, partly because there is a dearth of evidence-based programmes to address alcohol use during pregnancy that are acceptable to pregnant women, feasible for CHW delivery and suitable for the local context.

The current study is a first step towards developing a programme for pregnant women with alcohol problems that can be integrated into CHW-delivered maternal and child health services. This study aimed to explore pregnant women's explanatory models of alcohol use and perceptions of the acceptability, feasibility and barriers to accessing a community-based programme for pregnant women who drink from the perspective of pregnant women who drink, CHWs and Antenatal Service Providers (ASPs).

2. Methods

2.1. Setting and recruitment

The current study is presented in line with consolidated criteria for REporting Qualitative research (COREQ) guidance (23). We conducted face-to-face and telephonic in-depth interviews with CHWs, ASPs and pregnant women who drink alcohol. Interviews explored alcohol use amongst pregnant women; barriers to service engagement; how to enhance the uptake of a proposed intervention; perceptions of acceptable and appropriate counselling delivery agents; settings in which to deliver counselling; and methods of counselling delivery (e.g., acceptability of face to face individual sessions). For the latter, we were particularly interested in the perceived feasibility and acceptability of CHW delivered screening and interventions. The topic guides are included in Annexure A-C. Pregnant women were recruited from communities in the Cape Flats region of the Western Cape province. CHWs and ASPs (i.e., midwives and nurses) who are working in the Western Cape with women who are at risk of heavy drinking were eligible for inclusion. Pregnant women were identified through outreach activities by visiting areas frequented by potential participants and which were pointed out by community leaders and CHWs who helped identify initial contacts. These women were approached by research staff who explained the study to them and if

they were interested women were screened and either taken to the research site immediately to be interviewed or an appointment made for a time that was convenient for them. We then used snowball sampling from the initial contacts who identified peers who were pregnant women who drink alcohol. Through this peer-driven social network sampling all women identified by peers and who were approached accepted to take part. The pregnant women were required to be 18 years or older, report heavy drinking (defined as at least 1 day of drinking more than 4 drinks in the last month) measured using the Alcohol Timeline Follow Back, and screen positive for hazardous alcohol use (Alcohol Use Disorders Identification Test (AUDIT) score ≥ 8) (24).

2.2. Procedures

Interviews were conducted by the second author and project-coordinator (JE) who is female and has a post-graduate degree and more than 5 years qualitative research experience. JE had no prior relationship with study participants. Interviews were audio-recorded before being transcribed verbatim and lasted up to 60 min. Interviews took place between December 2020 and March 2021. Participants were reimbursed ZAR100 [~US $5.42 (ZAR18.45/$1)] for their time.

2.3. Analysis

NVivo 12 was used to store data and facilitate analysis. Results were analysed thematically using the Braun and Clarke approach (25). Data were analysed using a deductive approach to coding based on the research questions, which was combined with an inductive approach to allow other emergent themes to be identified. The second author (JE) conducted the initial process of familiarisation through a review of transcripts and coding. The first (PPW) and second author discussed the initial framework. After coding of initial transcripts, they discussed refining of codes and initial themes. Coding then continued of all interviews. Any coding disagreements were resolved through discussion and consultation with the last author (DF). Following this, themes were reviewed, defined and named as per Braun and Clarke guidelines.

2.4. Ethical approval

The study was approved by the South African Medical Research Council's (SAMRC) ethics committee (EC006-4/2020) and further approval from the Western Cape Health Department (WCDoH) (WC_202006_046) to conduct research with healthcare professionals was granted. All participants provided consent to participate in the study. Women were provided with referrals for available services. Face-to-face interviews were conducted at CHWs and ASPs place of work in a secure and private room. Face-to-face interviews with pregnant women were conducted in a secure and private room. For telephonic interviews with pregnant participants ($n = 2$), both were asked to provide a convenient time for the interview to be conducted and these interviews occurred when the two participants were alone. Confidentiality and anonymity were assured in that all data would be aggregated before presentation and no names mentioned.

3. Results

The results are classified into three major themes: alcohol use and pregnant women; barriers to accessing care; and perceptions of a counselling programme for problem alcohol use in pregnancy.

3.1. Sample characteristics

In total we conducted 28 interviews ($n = 5$ CHWs; $n = 8$ ASPs; and $n = 15$ pregnant women) before data saturation was reached, in line with recommendations for thematic analysis (26–28). The five CHWs were employed by an NGO that delivers comprehensive wellness services in response to communicable diseases. The ASPs consisted of eight midwives working in four PHC facilities, with the majority of women accessing these services being socio-economically disadvantaged. All CHWs and ASPs were female. The mean age of the pregnant women was 24.9 years (range 19–41 years), one was Black African and 14 were coloured (of mixed-race ancestry). AUDIT scores ranged from 9 to 30 with a mean score of 18.1 (SD = 5.9) and 10 (67%) scoring in the likely dependence range (AUDIT ≥15).

3.2. Alcohol use and pregnant women

3.2.1. Subtheme 1: extent and perceived causes of alcohol use amongst pregnant women

Participants discussed the prevalence of alcohol use amongst pregnant women and factors influencing drinking behaviour. The CHWs confirmed that during their work they often encounter pregnant women who drink alcohol. Reasons for drinking ranged from stressors related to not being able to financially provide for their families, troublesome romantic relationships, to ignorance about the effects of alcohol during pregnancy.

Especially for the adults also that's drinking, maybe they have a problem in the house, you know like money, food and stuff like that. Now you rather go drink, to forget that the children need this (CHW003).

You know how it goes, sometimes your boyfriend or husband makes you angry or there are problems like the fact that he does not work or there is no income, then you might feel like taking your last money and going drinking. (P011).

Participants described similar reasons for why pregnant women drink, with relationship difficulties, intimate partner violence, and ambivalence about the pregnancy being the most salient amongst these.

If they want to spite the boyfriend and say, I want to hurt your child or so, now I'm going to show you that I'm going to drink. I do not want the child, I want it to come down [miscarry]. People talk like that, just because they see that the boyfriend has another girlfriend (CHW001).

3.2.2. Subtheme 2: acceptability of alcohol use in pregnancy

CHWs reported that at a community-level alcohol is not recognized as a harmful substance or viewed as negatively as other substances therefore normalizing its use.

Yeah, it's like in the community everybody is labelled because you are doing drugs but nobody is labelled because they drink… like I said people now do not really see it as a problem (CHW005).

Pregnant participants reported a range of drinking patterns, with only a few drinking less since pregnancy recognition indicating its acceptability. However, although drinking was common, all the pregnant participants viewed their alcohol use as unacceptable and thought they should be drinking substantially less.

During the week I do not even think about that, but when Friday comes by, Saturday morning I'm stressed out, tired and I'm kinda like a glass of wine and then it will be a second one, third one and then it ends up being 5 litres. It's just that I cannot control it, if I could I would stop (P006).

3.2.3. Subtheme 3: knowledge of impact of alcohol use in pregnancy

Many pregnant women shared the correct information and expressed concern about how alcohol use could affect their unborn infant. However, some pregnant women lacked this understanding or were indifferent to the effects of alcohol.

Yes, because I was drinking when I had my first and second babies and they came out normal, so why must I quit if my children came out normal? (P007).

No, I'm not that concerned. I feel life inside of me every day, it's not that it's quiet, so I feel happy (P009).

3.3. Barriers to accessing care

3.3.1. Subtheme 1: alcohol use as a barrier to service engagement

Participants described alcohol use as a barrier to antenatal service engagement. ASPs shared their experiences of late initiation of antenatal care and/or irregular attendance of scheduled appointments by pregnant women who drink alcohol. They reported how some women who drink arrive at the clinic when they are in labour without any prior antenatal care. They also described instances where women arrived at the labour ward drunk claiming to be in labour, but once checked there were no signs of labour which they believed due to their intoxication. They reported that these incidences place additional burden on the clinic staff, especially where they are understaffed, and have low resources. According to ASPs, these limited resources affect their ability to provide pregnant women who drink with alcohol-related health education and to refer women for alcohol-related services.

3.3.2. Subtheme 2: relationships with service providers

ASPs felt that pregnant women who drink were fearful of attending their clinic sessions, especially when they knew any of the nurses in a personal capacity. Staff working in PHC facilities often reside in the same area where they work.

Stigma in that they do not want to come because this person knows them here, that person knows them (ASP005).

CHWs shared reports from pregnant women who experienced negative reactions from nurses about their alcohol use during their antenatal clinic visits. They thought that these stigmatising interactions hindered some pregnant women from accessing services.

Yes. How do I say it – it is not good to judge and shame people in public; "Look how you look." "You're smelling." That will not work. Or if the child is underweight; "You did not breastfeed them properly" (CHW001).

Pregnant women admitted to not disclosing their alcohol use during their health screening as they anticipated and feared negative reactions from nurses. Nurses acknowledged that their style of communicating with pregnant women who drink was not ideal.

ASPs described trying to instil fear and scare patients in the hope that they will either disclose their alcohol use or change their drinking. As one pointed out:

So you have to interrogate the hell out of them. Because normally what they tell you is not what it seems. They will not tell you that they drank last night but you can smell it so I'm like no but you did drink… I do not let up. I'm relentless. Many other people will just like leave it. I'm relentless. I will ask you. If you go into labour now and that water broke and it smells like alcohol do you know your baby can die (ASP004).

3.3.3. Subtheme 3: partner relationships

All three groups of participants described relationships with romantic partners as a barrier to care. According to ASPs, these relationships often influence pregnant women's use of antenatal services, especially where these relationships were violent.

And also you talk about the gender-based violence to them because others they are abused at home that is why maybe they are not going to the clinic, or else they are depending to the alcohol. Things like that (ASP001).

3.3.4. Subtheme 4: alcohol screening and referral for treatment

It was apparent that screening and referral for alcohol use was not a rigorous process. ASPs described alcohol screening as being part of the mental and health screening process at the first appointment and consists of only one question: "Do you drink alcohol?" If a patient responds "No," then the nurse is not able to move forward with a referral for alcohol-related services. Even if the patient discloses alcohol use, ASPs are only able to offer a referral if a process is in place. All ASPs reported providing a 5-min information session on healthy pregnancy that addresses FAS, if a pregnant woman discloses alcohol use. However, they did not clarify whether this alcohol education was provided to women who did not disclose alcohol use.

ASPs felt that pregnant women were not always forthcoming about their alcohol consumption, either denying any alcohol use or underreporting their consumption. Given the reliance on self-disclosed alcohol use for referral, this was viewed as a barrier to offering appropriate and effective assistance to pregnant women who drink.

The patients lie. The patients do not say the truth. They will say they do not drink, but then they do. But we do not have any proof. So, we have to take the word as they say it, and most of them do not admit to alcohol (ASP005).

Similarly, CHWs shared that pregnant women's nondisclosure of alcohol use affected their ability to refer women for additional care. Whilst CHW service delivery did not include routine screening for alcohol use, they did describe offering education and information on the dangers of drinking whilst pregnant if they suspected alcohol use.

CHWs also described some difficulty in getting pregnant women to accept help for their alcohol use. They thought this was due to a lack of trust in available services and support.

"I do not need health education. I can cope and raise my child on my own. And my child will be fine." They do not understand that we are just here to support and be on standby, not to judge them (CHW001).

Pregnant women considered the screening process at antenatal services as problematic. They reported receiving very little to no education on guidelines for alcohol use during pregnancy or counselling for alcohol-related difficulties.

They said they cannot tell me not to drink, but I should know my limits. I told them that it's only 2 to 3 beers a day (P010).

There was no counselling, nothing!… Yet on my maternity book it states that I needed counselling yet I did not get it. (P003).

3.4. Perceptions of a counselling programme for alcohol use in pregnancy

All three groups of participants were asked their opinion on a counselling programme for alcohol use for pregnant women and their perceptions of the feasibility and acceptability of CHW-delivered screening and interventions. As an example, we summarized counselling for alcohol problems (CAP), a lay-delivered community-based intervention to reduce alcohol use (29). CAP is a manualized brief psychological therapy based on motivational interviewing and behavioural techniques such as problem-based management and cognitive behaviour therapy. It is currently the only available evidence-based alcohol-focused brief therapy delivered in community settings by lay counsellors in a low– and middle-income country (LMIC) (29, 30).

3.4.1. Subtheme 1: feasibility and barriers to accessing a community based programme for pregnant women

Despite raising some anticipated delivery challenges, all three groups responded positively and confirmed the need for such a programme. CHWs discussed the opportunities they have to include counselling for pregnant women who use alcohol and the feasibility of being delivery agents. CHWs shared the opportunities they have to impact early pregnancy recognition and to refer pregnant women to antenatal services and other support services where these are available.

Pregnant women reflected on how a counselling programme would benefit them, especially as they had no support for alcohol-related difficulties.

Because why they going to be in a programme, so this programme it will be almost like a rehab, now these things that you going to give us to do in the house and so (P001).

3.4.2. Subtheme 2: acceptability of and recommendations for a community based programme for pregnant women

All participants reacted positively to the content of a community-based alcohol programme, and pregnant women particularly liked the idea of having CHW support for healthy choices during pregnancy.

That will be great idea to have someone whom you can come to, help you with solution in life, at the end of the day that person is needed for better decisions, coming with better ideas and solutions… Of course other women will love this, I know most of them they are bored at home and they would love conversations that are helping and sometimes you need to take up a different challenge (P003).

Whilst a few participants thought an intervention could be clinic-based, the majority thought that the community would be the ideal implementation setting for such an intervention. Participants did however note that CHWs would need to consider whether women's homes are safe and empowering settings for interventions, highlighting the prevalence of gender-based violence. These factors would need to be taken into consideration when deciding the location or venue for services.

I think it's a good thing but then again, it depends on the community you work in, like a lot of the time the abuser is in the home. And that woman is not going to open up… but then this person might discourage this woman also to not come to this place (CHW002).

Participants all thought there should be multiple intervention sessions ranging from twice a week to twice a month, up to four to six times, over several months of the pregnancy. Suggestions for the duration of the sessions ranged from as short as 5 min, up to 2 h. Whilst ASPs thought midwives could deliver the intervention, CHWs and pregnant women felt CHWs were best placed as the delivery agent. There were mixed views about whether the intervention should target all pregnant women (so as not to miss those who deny drinking) or be restricted to those women who report alcohol use.

Several clinic and community challenges to implementation were raised. Firstly, clinic-level challenges included shortage of space, staff capacity, high number of pregnant women, long waiting times, financial burden of having to travel to a clinic, lack of comfort and privacy and staff attitudes. Community-level challenges included crime, lack of privacy, lack of attention given competing interests in the home, fear due to abuse, and stigma and discrimination from other community members. Suggestions for overcoming these challenges included providing individual sessions rather than group sessions, using whatsapp groups for support and communication, providing vouchers and also something to eat and drink at the sessions and the addition of peer support groups. Finally, participations recommended the inclusion of additional intervention content related to breastfeeding, family planning, termination of pregnancy, recreational activities, exercise, nutrition and healthy eating and life skills training. All participants thought intervention content should be reinforced through the provision of information pamphlets or an intervention booklet.

Table 1 summarises the proposed components of a community-based alcohol programme based on what all three groups of stakeholders consider relevant, appropriate, and feasible to deliver (see Supplement 1 for *more detail on this stakeholder feedback*).

4. Discussion

Alcohol use amongst pregnant women is perceived by healthcare providers to be widespread and pregnant women themselves report high levels of drinking despite having some insight into the negative impact of their drinking on their unborn infants. Several barriers to accessing care were identified in the current study including the influence of alcohol consumption on antenatal service attendance and a shortage of resources preventing adequate screening, education and referral for alcohol use. Findings suggest that alcohol use during pregnancy is under-detected due to inadequate screening processes. There is a need to reevaluate screening processes and procedures so that more time is spent on building rapport and an enabling environment in which women feel comfortable disclosing alcohol use. In keeping with other studies (31–33), emphasis was placed on non-disclosure by pregnant women being the reason for the lack of care pregnant women with alcohol problems receive. It has also been suggested that the absence of a formal alcohol

TABLE 1 Proposed elements of a community-based intervention for pregnant women who are drinking.

Intervention component	Proposed for intervention
Venue	5 individual sessions in the home, monitored by progress, and extended if necessary
	Pregnant women move on to Support group for the rest of their pregnancy
How often?	Once a week for 5 weeks (max over 8-week period), with homework between sessions.
For what period?	Individual sessions 5 weeks – to be completed over an 8-week period if needed (exploration of final session as group)
Time taken for each session?	Individual sessions: 30–60 min; support group sessions 2–3 h
Level of drinking	Individual sessions for all pregnant women who report drinking above recommended guidelines in pregnancy
Challenges to the clinic	Challenges mentioned: space, staff capacity, high number of pregnant women, long waiting times, financial burden of having to travel to clinic
Facilitation of implementation	Making use of the following: Whatsapp groups A certificate of completion after each session; to monitor their own progress Pregnant women to sign a document as a commitment to the programme for themselves and baby. Engaging activities and games at support group Involving external service providers such as Dietician, dentistry etc. to provide service at support group Provision of food and refreshments Include a small gift once entire programme is complete (Month before due date)
Additional components	Mental health Use of other substances, and over the counter/prescription medications Family planning Breastfeeding Wellbeing of baby Safe exercises routines Nutrition – how to eat well on a low budget. Arts and crafts Development of a skill (eg: making something for your baby) Significant other to attend the first session – providing them with a brochure and guiding them on how to be supportive and as someone for the pregnant women to be accountable to
Perceived acceptability of programme	Pregnant women, CHWS and ASP, were generally positive and supported the overall programme. Pregnant women were accepting of the involvement of a 'significant other', on the condition that it is not mandatory, as often, they do not have a sober-living partner, or family member who they think could support them.
Resources	Making use of pamphlets for the significant other, and a manual that they can take home, and go through themselves, a drinking diary to monitor their progress

screening and intervention protocol in antenatal services impacts on the care that pregnant women who drink receive (31). Similarly, referral systems and support structures were described as lacking in healthcare facilities and in the community. This is not surprising as other studies have highlighted the lack of referral pathways for patients attending primary care clinics who disclose problems related to alcohol use (34, 35). Unclear or non-existent guidelines for referring women for non-medical reasons related to alcohol use limits the extent to which women are able to access the services they need. There is thus a need to formalise a referral pathway and to develop and formalise processes for how to refer patients to these services as part of a programme of care for women who drink in the community.

It was noted that staff attitudes and approach may be preventing effective care and service provision. Changing the messaging from one that is confrontational and condescending, to one that is motivational, and non-judgmental is what pregnant women would deem a safer environment for them to comfortably disclose their alcohol use. The role of stigma on alcohol disclosure and on access to health services and how stigmatising attitudes from health providers towards patients who drink and the impact this has on health service use and alcohol outcomes has been highlighted in earlier studies (36, 37). Amongst pregnant women, studies have shown that fear and stigma may hinder women from accessing antenatal and other health services or disclosing substance use (38). Whilst medical assessments and procedures were reported as adequate, caring inter-personal relationships and interactions were reported to be lacking. Providing SPs with training on relationship and trust building and how to create safe spaces is crucial. CHWs noted that current activities and model of service provision enables the inclusion of counselling for alcohol-related problems. Being able to integrate the proposed activities into an already existing structure in the community would save costs and would also advance the skills development of the staff. CHWs can additionally be upskilled to provide some of the additional intervention components recommended in this paper.

Importantly, this counselling programme would need to be offered as part of a whole systems approach to supporting women with alcohol problems. As a brief therapy comprising at least five

sessions and offering ongoing monitoring and support for alcohol change, it is best suited for women with AUDIT scores <20 (in keeping with WHO guidelines) (24). We acknowledge that additional services will be needed to support women with higher AUDIT scores indicative of alcohol dependence. With limited access to and lengthy wait times for specialist alcohol services in South Africa and no services tailored to the needs of pregnant women (39, 40), we propose delivering this counselling programme as part of a stepped care approach to treatment. In this model, women with AUDIT scores indicative of dependence are referred for specialist services but have an opportunity to access and benefit from this community programme whilst they wait to access specialist care.

Given the workforce constraints in low-resource settings, task-sharing approaches where non-specialist workers such as CHWs deliver evidence-based psychosocial interventions for alcohol use are being promoted as feasible, acceptable and cost effective (41, 42) and supported by South Africa's health policies (43). Case studies from other parts of Africa and Asia similarly demonstrate that CHWs are well positioned geographically and socially to deliver some aspects of maternal and newborn health (MNH) (44) and alcohol interventions [37]. The proposed programme may therefore be relevant in settings similar to SA where lay counsellors are positioned to deliver psychosocial interventions. CHWs shared many challenges they currently face in their day to day activities, which mirrored the challenges they preempted from the proposed programme. Challenges such as lack of privacy, safety in the home of the pregnant women, unsafe areas, and engaging with women who are not forthcoming in advancing their relationship with the CHWs. These challenges need to be addressed in developing a counselling programme for pregnant women with alcohol problems, and CHWs themselves made recommendations for how to overcome some of these barriers. They recommended that a programme of care for pregnant women with alcohol problems is delivered in women's homes and that change in alcohol use is monitored. The opportunity for early referrals to antenatal clinics and early initiation of antenatal care exists and will increase overall wellbeing of mom and baby.

Contrary to other studies conducted in the same region where pregnant women were largely unfamiliar with FASD or had limited knowledge of the impacts of drinking during pregnancy (45), many pregnant women in the current study were informed about the effects of alcohol use in pregnancy. Therefore, interventions need to address psycho-social struggles, particularly related to experiences of stress, interpersonal relationships and experiences of violence and move beyond information sharing and education to support women to reduce their drinking. As reflected in the suggested additional components, addressing mental health and providing a holistic integrated programme of support to pregnant women with alcohol problems, such as the desired sessions on family planning, breastfeeding and nutrition, exercise, and skills development, may lead to improved retention in antenatal care, and improved maternal and child outcomes.

This is the first study that sought to assess the potential feasibility and acceptability of a counselling programme for pregnant women with alcohol problems in the Western Cape. We could capture the experiences of women with regards to their drinking and we were able to assess current barriers to accessing services from a range of stakeholders. However, there are some limitations to consider. First, there may have been social desirability bias particularly from ASPs and CHWs who may be invested in seeing a programme developed to prevent drinking in pregnancy. Second, it is possible that some recall bias related to the extent of alcohol consumption may have been present. Third, given the inclusion criteria, all pregnant women were drinking at hazardous or harmful patterns. Since no drinking in pregnancy is recommended, it may have been useful to include participants reporting any use of alcohol rather than using general population cut-off points on the AUDIT to guide recruitment. This inclusion of heavy drinkers only may bias acceptability, which may not be generalizable to all pregnant women who drink. Finally, given the peer-driven recruitment, findings are limited to a particular social network of pregnant women with problem alcohol use.

5. Conclusion

Findings from the formative research are being used to design a counselling programme for pregnant women with alcohol problems that may be acceptable, feasible and culturally appropriate for the local context. These findings will inform the development of an intervention protocol and field manual to be tested in a feasibility study of the relevance, appropriateness and acceptability of the programme.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by South African Medical Research Council's (SAMRC) ethics committee. The patients/participants provided their written informed consent to participate in this study.

Author contributions

PP and DF conceptualized the study. JE conducted the qualitative interviews. PP and JE conducted the analysis and PP prepared the manuscript first draft. BM and AN helped develop and refine the study and all authors revised the draft versions of the manuscript critically. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2023.1203835/full#supplementary-material

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Knowledge, attitudes, practices, and beliefs regarding prenatal alcohol consumption among women in Leyte, the Philippines

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Objectives: Fetal alcohol spectrum disorder (FASD) captures the broad range of emotional, cognitive, behavioral, and congenital abnormalities associated with maternal alcohol consumption, and women living in resource-limited settings may be higher risk. This study aims to examine knowledge, attitudes, practices, and beliefs (KAPB) of women in Leyte, The Philippines regarding prenatal alcohol consumption.
Methods: One hundred postpartum women were recruited from a birth cohort in Leyte. A prenatal alcohol use KAPB survey was constructed in Waray, the local language. The survey was administered in June-September 2019. Descriptive statistics, chi-squared test, and Fisher's exact test were used to analyze responses.
Results: Seventy-five percent of subjects reported drinking tuba, a local palm wine, during pregnancy. Most participants (75%) did not believe tuba contained alcohol. Women who believed tuba contains no alcohol were more likely to drink tuba during pregnancy (81.3%) than women who believed tuba contains alcohol (56.0%), $X^2(1, N = 100) = 6.41$, $p = .011$. Women who drank tuba during pregnancy were more likely to believe tuba has health benefits (60%) than women who did not drink tuba during pregnancy (12%), Fisher's exact $p < .05$, citing increased red blood cell count and unproven antiparasitic qualities. Fifteen percent of subjects reported having fed their babies tuba. Nearly all (98%) were willing to attenuate tuba/alcohol consumption if told that this practice negatively impacts pregnancies.
Conclusion: Misinformation about tuba appears widespread in Leyte. Educating women of reproductive age in Leyte regarding prenatal tuba use may lead to a reduction in tuba use.

KEYWORDS
alcohol, prenatal, LMIC, FASD, tuba, KAPB

Detailed key findings/implications

- Currently, little is known about prenatal alcohol consumption and FASD in low- and middle-income countries (LMICs). FASD is entirely preventable if pregnant women abstain from alcohol during pregnancy. It is likely that women in resource limited settings, such as Leyte, The Philippines, may be at high risk of giving birth to children

with FASD due to a lack of systemic preventative education surrounding alcohol use in pregnancy, later confirmation of pregnancy, and consumption of unregulated alcohol brews that are locally made. This study examines the knowledge, attitudes, practices, and beliefs surrounding prenatal alcohol consumption, with a focus on tuba, a local, unregulated and commonly consumed palm wine in Leyte, The Philippines.

- Our findings are potentially generalizable to other regions of the world, specifically LMICs, where similar practices exist. Per this study, many women may be unaware that locally fermented beverages contain alcohol and that alcohol may harm the fetus. Thus, opportunities exist to target interventions that address this knowledge gap, helping decrease the risk of fetal alcohol spectrum disorder worldwide.
- Misinformation about tuba as an alcoholic beverage appears to play a role in the practices surrounding maternal and pediatric tuba consumption in Leyte, The Philippines. Most participants in our study reported consumption of alcohol during pregnancy. Future work should focus on incorporating tuba screening into already existing structures for alcohol and tobacco smoking screening at prenatal visits. Data from this study can inform local health departments in the creation of health education materials and/or programs addressing prenatal alcohol use for women of childbearing age.

Introduction

In 1973, "fetal alcohol syndrome" (FAS) was coined to describe the cluster of birth defects with lifetime consequences due to prenatal alcohol exposure, including craniofacial abnormalities, growth restriction, and intellectual disabilities (1–3). Since then, the umbrella term "fetal alcohol spectrum disorder" (FASD) has been adopted to capture the broad range of emotional, cognitive, behavioral, and congenital abnormalities associated with prenatal alcohol exposure (1, 3–6). A number of large meta-analyses have estimated the global prevalence of FASD; among children and youth in the general population this has been estimated to be 7.7 per 1,000 (7) and among the general population, 1.46 per 1,000 (8). Of relevance to this study, some of the highest rates of FASD globally have been noted in LMIC nations (65.2–74.2 per 1,000 children) (9). Notably, this disorder is entirely preventable if pregnant women abstain from alcohol consumption (6).

Mothers of children with FASD are often shamed for having what is viewed as problematic patterns of alcohol use (10). The belief that pregnant women drink alcohol despite knowing its effects on their fetuses ignores complex sociocultural factors at play. Population and qualitative studies have shown that many mothers of children with FASD do not have alcohol use disorder (11–13). For example, a qualitative study conducted in New Zealand involving biological mothers living with their FASD-affected children revealed that many were unaware of the effects of prenatal alcohol exposure and had no knowledge of the potential risk of alcohol intake while pregnant (12). Systematic reviews across many settings reveal multiple reasons for pre-natal alcohol consumption including lack of awareness of harm and even perceived benefit, peer and cultural influences that continue during pregnancy, and others (14, 15). Additional risk factors for giving birth to children with FASD include lower maternal education level, lower socioeconomic status, paternal drinking and drug use at the time of pregnancy, reduced access to antenatal care and services, inadequate nutrition, and a poor developmental environment (e.g., stress, abuse, neglect), among other factors (16).

The global prevalence in the general population of consuming any quantity of alcohol during pregnancy has been estimated to be 9.8% (8). It is likely that women living in resource-limited settings, specifically in LMICs, may be at higher risk of giving birth to children with FASD. This increased risk is multifactorial and includes factors such as lack of systematic preventative education surrounding alcohol use during pregnancy and potential harms, later confirmation of pregnancy, and consumption of unregulated alcohol in the form of local or homemade alcoholic brews produced and sold outside of government control and without warning labels (17–19). This is pertinent to Leyte, The Philippines, where the most commonly consumed alcohol is a largely unregulated alcoholic beverage—a locally fermented palm wine called tuba (20, 21). We previously analyzed two tuba samples from Leyte to quantify the alcohol content: one from a home in one of our study villages and the other from a local shop. Both samples contained 7.3% ethanol by gas chromatography.

In an NIH funded, randomized-controlled trial in Leyte, The Philippines, over 75% of subjects reported continued alcohol consumption at 12–16 weeks gestation (20). No studies to our knowledge have examined this population to determine what underlying factors result in such high alcohol consumption rates. This study employed a survey assessing the knowledge, attitudes, practices, and beliefs (KAPB) surrounding prenatal alcohol consumption in Leyte, The Philippines in order to better understand what factors may influence mothers' decisions to consume alcohol during pregnancy.

Methods

Study population

Participants were recruited from an ongoing NIH-funded longitudinal birth cohort designed to examine the interactions among alcohol, helminth infections, and undernutrition in mediating adverse pregnancy outcomes (NIH R01AA024092). The main study enrolled 400 expectant mothers from over 50 villages served by 8 municipal health centers in northeastern Leyte, The Philippines. Participants were deemed eligible if they were otherwise healthy, ≥18 years of age, and had a verified singleton intrauterine pregnancy. Eligibility criteria were determined by history, physical exam, ultrasound, and laboratory assessment. For this study, a convenience sample of $N = 100$ women from the main study were sequentially enrolled during their child's planned follow-up visits (6–24 months postpartum) from June to September 2019 when staff were available to

administer the questionnaire during these scheduled visits. All subjects provided their informed consent prior to inclusion.

Knowledge, attitudes, practices, and beliefs (KAPB) survey

The survey was administered during the child's follow-up visits at the Research Institute of Tropical Medicine's satellite laboratory in Palo, Leyte, The Philippines from June to September 2019. (See appendix for full survey.) The survey was constructed using the instrument "Alcohol and Pregnancy Questionnaire" as a scaffold under express permission from the author (22). The KAPB survey was developed and greatly modified with input from local stakeholders in order to increase relevance to the study population and account for participant literacy levels. Initially constructed in English, the survey was translated into written form in Waray, the native language of the Eastern Visayas. Translation was jointly performed by multiple native speakers of Waray and back-translated to ensure accuracy. The questionnaire was then verbally administered by trained staff due to variability in literacy rates among participants. The questionnaire was initially pilot tested with six mothers and was subsequently modified to ensure clarity and survey comprehension. The instrument was comprised of 28 close- and open-ended questions. Closed ended questions were included (a) true/false, (b) yes/no, (c) rating a scale from 1 to 4 from "not important at all" to "very important, " and d) selected choices such as type of alcoholic beverages which always included an "other" option. The following domains and the number of questions asked for that domain included: (1) perceived importance of maternal health during pregnancy as a means of promoting fetal health, ($N = 6$) (2) knowledge that tuba is an alcoholic beverage ($N = 1$), (3) self-reported behaviors regarding alcohol consumption before and during pregnancy ($N = 6$), (4) perceived risks or benefits of alcohol consumption during pregnancy ($N = 4$), (5) behaviors regarding infant alcohol consumption ($N = 3$), (6) perceived risks or benefits of infant alcohol consumption ($N = 2$), (7) receptiveness towards behavior change if informed of the negative effects of alcohol ($N = 2$), (8) potential influence from external sources (family, friends, and physicians) regarding tuba consumption ($N = 2$), and (9) perceived interest in gaining additional information regarding maternal and fetal health ($N = 2$). For open-ended questions, responses were aggregated into categories based on common themes. Of note, question 13 was limited to 90 respondents due to delayed addition of the question to the instrument.

Statistical analysis

Survey data was recorded and managed using Microsoft Excel and Filemaker Pro (Claris, Santa Clara, CA). Descriptive statistics along with Pearson's χ^2 tests were utilized to analyze survey response data. For proportions with smaller numbers in a specific subgroup or "cell" Fisher's Exact testing was employed. For all analyses, a p-value of <.05 was considered significant. Stata statistical software version 16 (StataCorp LP, College Station, TX) was used for data management and statistical analyses.

Ethical statement

The study was approved by the Institutional Review Board at Rhode Island Hospital and The Ethical Review Board of the Research Institute of Tropical Medicine in Manila, The Philippines.

Results

One hundred women participated in the study. Participants resided in one of 39 barangays, or villages, in three different municipalities in the province of Leyte, The Philippines: Alang-Alang, Jaro, and Santa Fe. **Table 1** lists the sociodemographic characteristics of participants as captured during their pregnancy during the main study.

During our survey, 75 women (75%) reported drinking tuba or other alcoholic beverages during pregnancy. Of the women who reported drinking tuba or other alcoholic beverages, 100% reported specifically drinking tuba during pregnancy while only 5.3% ($n = 4$) reported drinking beer. Participants did not endorse consuming any other form of alcohol during pregnancy. Self-

TABLE 1 Sociodemographic characteristics of the participant ($N = 100$).

Variables	N	%
Mother's age at time of survey (years)		
Mean	28.6 (5.3)	
Minimum, Maximum	21, 44	
Median	28	
Highest education[a]		
None	1	1
Elementary	25	25
High school	61	61
College	11	11
Vocational School	2	2
Does participant smoke?[a]		
Yes	0	0
No	100	100
Did participant smoke in the past?[a]		
Yes	8	8
No	92	92
Does participant drink tuba/alcohol?[a]		
Yes	69	69
No	31	31
If yes, how many years drinking?[a]		
Less than a year	7	7
1–5	46	46
6–10	12	12
11–15	1	1
16–20	3	3

[a]Signifies data captured prenatally (i.e., upon initial enrolment of subjects in longitudinal birth cohort study).

reported estimates of weekly prenatal tuba or other alcohol consumption are noted in Figure 1.

Participants were surveyed regarding the perceived importance of reducing alcohol consumption relative to other known healthy behaviors (Table 2). Almost all (97%) of mothers considered nutrition, exercise/physical activity, visiting a doctor or health professional, and reducing/stopping smoking to be either "important" or "very important," while only 60% of participants considered decreasing the consumption of tuba or other alcoholic beverages during pregnancy "important" or "very important."

When asked if tuba contains alcohol, most participants (75%) responded "No." Nearly half (48%) answered "True" to the statement: "Tuba or other alcoholic beverages are good for you and the baby while you are pregnant." Women who indicated that tuba or other alcoholic beverages have health benefits (48%) were asked to describe said benefits in open-ended format (Table 3). Similarly, participants who responded "False" (52%) selected from a variety of reasons supporting their belief and/or listed other reasons not captured by the multiple choice format (Table 3).

Overall, 15% ($N = 15$) of participants reported giving tuba or another alcoholic beverage to their youngest child within the first year of life. Of these respondents, 100% reported giving their child tuba and no other alcoholic beverage. Of 15 participants who gave their child tuba, most (87%) gave their child less than 1 teaspoon of tuba per day. None reported giving their child more than 2 teaspoons of tuba per day. The reasons participants gave regarding whether or not to feed their baby tuba are described in Figures 2A,B.

Participants were asked if their families or friends encouraged them to drink tuba while pregnant and most (59%) responded "yes." In response to "Did your doctor explain to you the effects of drinking tuba during pregnancy?", 20.0% of participants ($n = 18$) reported "yes" while 48.9% ($n = 44$) reported "no." Overall, 31.1% of participants ($n = 28$) reported never having visited a doctor during the course of their pregnancy. Nearly all mothers (98%) reported "yes" when asked if they would cut back on their drinking if they were told that tuba or other alcoholic beverages have negative effects on them and their unborn child. Two participants (2%) answered "no", stating that they never personally experienced any side effects from prenatal tuba consumption. However, all of the women surveyed stated they would like to learn more about how to keep their baby/pregnancy healthy, with preferred modalities presented in Figure 3.

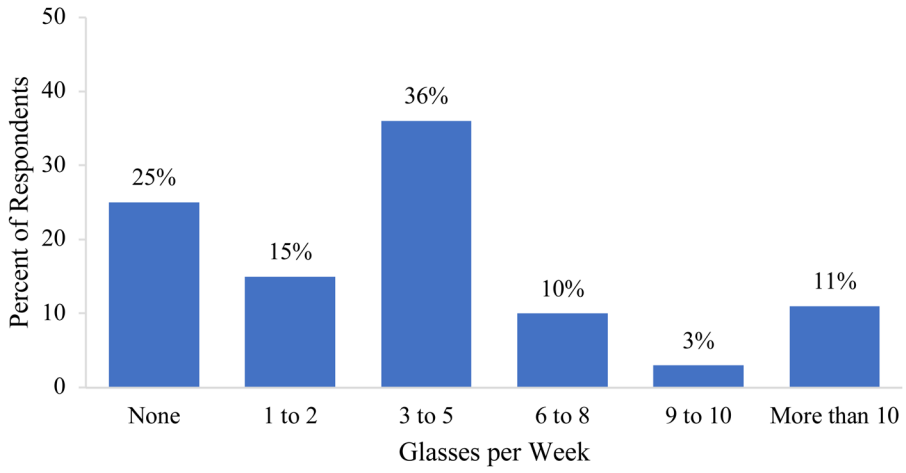

FIGURE 1
Self-reported estimates of weekly prenatal tuba or other alcohol consumption in glasses per week.

TABLE 2 Perceived importance of various health-related behaviors during pregnancy.

Health Pregnancy Actions	Very important	Important	Not very important	Not important at all
"How important was it for you to be healthy during your pregnancy to make it more likely for your baby to be born healthy?"	66	34	0	0
"I'm going to read some things that pregnant women might or might not do to make it more likely that their baby is born healthy. Tell me if you feel that these things are very important, important, not very important, or not important at all."				
Visit a doctor or health professional	77	22	1	0
Eat well/have good nutrition	80	20	0	0
Exercise/perform physical activity	35	62	3	0
Cut down or stop smoking	64	33	3	0
Cut down or stop drinking tuba or other alcoholic beverages	15	45	30	10

TABLE 3 Self-reported effects of drinking tuba or other alcoholic beverages during pregnancy.

What are some good effects of drinking tuba or other alcoholic beverages while pregnant?	*N*	%
Open-ended responses		
It increases red blood cell count	23	23
It increases lactation	14	14
It keeps the baby healthy	8	8
It provides good nutrition	7	7
It keeps the mother healthy	5	5
It improves the labor process	5	5
It has anti-parasitic properties	2	2
It helps the mother sleep	1	1
It relaxes the mother	1	1
What are some bad effects of drinking tuba or other alcoholic beverages while pregnant?	***N***	**%**
Closed-ended responses		
The baby may not grow as well and will be born smaller	39	39
Miscarriage	12	12
The baby can have cognitive or "thinking" problems	10	10
Stillbirth	9	9
The baby can have behavioral problems	7	7
Open-ended responses		
It causes dizziness/nausea	3	3
The child may become dependent on tuba	1	1
The mother has an aversion to the smell of tuba	1	1
It makes the child sick more easily	1	1
It causes hyperacidity	1	1
It causes congenital anomalies	1	1
It interferes with anesthesia	1	1
It does not affect the baby	1	1

Women who believed tuba contains no alcohol were more likely to drink tuba (81.3%) than women who believed tuba contains alcohol (56.0%), X^2 (1, $N = 100$) = 6.41, $p = .011$ (**Figure 4A**). Women who drank tuba during pregnancy were more likely to believe tuba has health benefits (60%) than women who did not drink tuba during pregnancy (12%), Fisher's exact $p < .05$ (**Figure 4B**).

Discussion

Though there remains some controversy regarding the risks to the fetus with consumption of low levels of alcohol pre-natally (23), there is currently no known safe threshold for prenatal alcohol consumption (24, 25). As such, it is particularly concerning that 75% of women in this cohort reported drinking alcohol while they were pregnant. These findings are consistent with the self-reported rates of prenatal alcohol consumption from a previous study conducted in Leyte with a different group of pregnant women, bolstering the reliability of these responses (20). Overall, we found that a high proportion of women continued to drink during pregnancy and that many were not aware of the harmful effects of alcohol use during pregnancy.

When asked about the importance of various health-related activities during pregnancy, a contrast was noted between activities related to alcohol consumption and all other health-related activities. Greater than 95% of mothers considered other behavioral changes to be either "important" or "very important." In contrast, only 60% of participants considered decreasing the consumption of tuba or other alcoholic beverages during pregnancy "important" or "very important." This suggests that tuba or other alcoholic beverages are not viewed in the same light as other unhealthy practices (e.g., smoking) and may not be prioritized for behavioral change. Given many women may not be aware that tuba contains alcohol, some may have also de-emphasized the importance of reducing consumption. Other studies in LMICs have also found that women are not aware of potential harms of alcohol during pregnancy and may, therefore, not modify these behaviors (12, 14, 16).

The majority of women who endorsed drinking "tuba or other alcoholic beverages" in the study exclusively drank tuba and no other alcoholic beverage. The majority of mothers did not believe tuba contained alcohol, and there was a significant association between self-reported prenatal tuba consumption and the belief that tuba does not contain alcohol. Of the mothers who believed that tuba or other alcoholic beverages were good for them and their baby, most (78%) deemed it "healthy" to consume three or more glasses of tuba/alcohol per week. This suggests a lack of understanding of the negative effects of tuba and/or other alcoholic beverages on the developing fetus, likely leading to a lack of moderation of prenatal alcohol intake. As well, these findings suggest that misinformation regarding the alcohol content of tuba may play a key role in the consumption of alcohol during pregnancy in Leyte. Unregulated brews such as tuba are not easily monitored, and consumers cannot rely on such brews having standardized pregnancy warning labels, such as those seen on government-regulated alcoholic beverages, which is an issue globally (19). Broader education campaigns and targeted screening provided during prenatal care visits could serve as platforms to disseminate information on the dangers of prenatal tuba consumption.

Recent systematic reviews also suggest multiple reasons for continued pre-natal alcohol use that likely vary across settings but with similar themes emerging. These include lack of awareness of harm and even perceived benefit, medical advice to continue, peer and cultural influences, and others (14). Our findings are concordant with many of these reasons. More than half of respondents reported being encouraged by family or friends to drink tuba while they were pregnant, suggesting that external influences may play a role in prenatal alcohol consumption in the community. Moreover, nearly half of the study participants reported that their doctor never explained the effects of drinking tuba during pregnancy. Several different possibilities could explain this finding: (1) tuba consumption during pregnancy is an under-recognized practice, (2) healthcare providers are also unaware of tuba's alcoholic content and its subsequent harm to the developing fetus, (3) there exists no standardized prenatal care practice in Leyte for healthcare providers to screen for tuba or other alcohol use, or (4) the majority of women in the Philippines receive prenatal care from midwives, and participants only answered the question as it

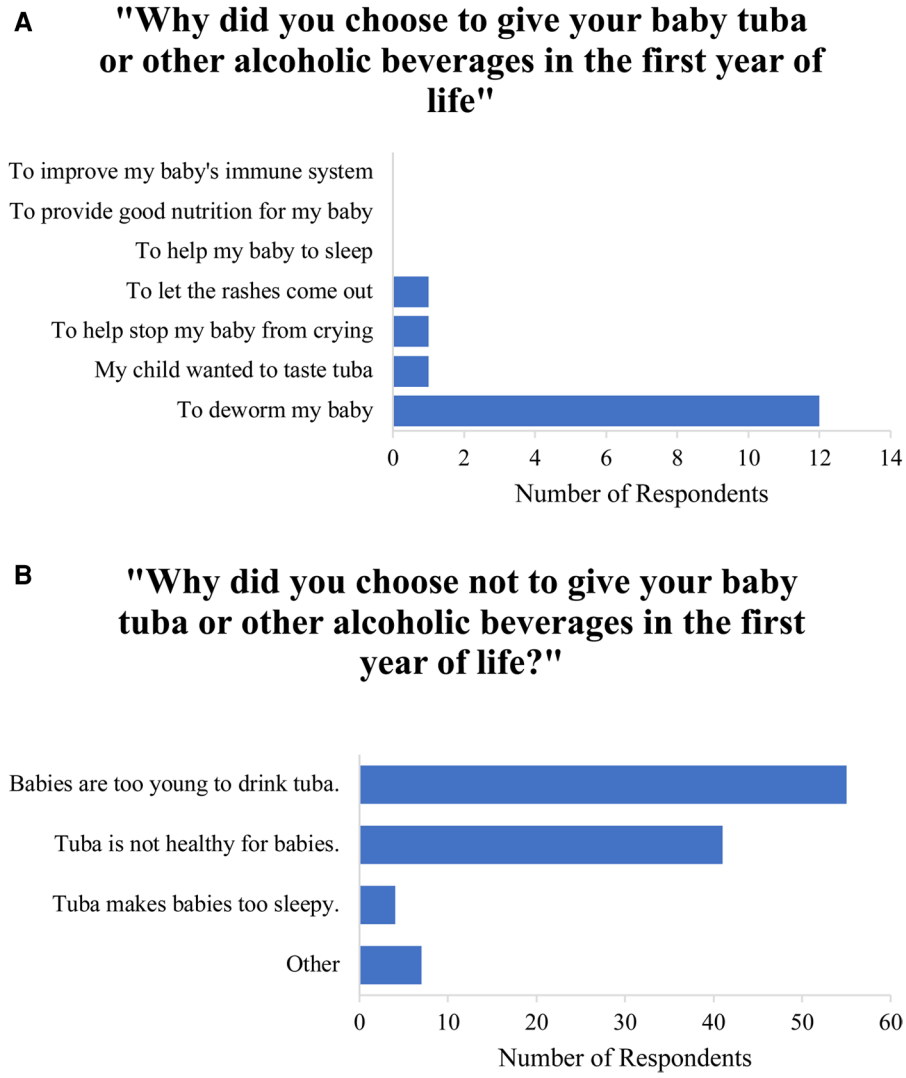

FIGURE 2
(A) Participants' cited reasons for feeding tuba or other alcohol to their babies. (B) Participants' cited reasons for not feeding tuba or other alcohol to their babies.

related to seeing a "doctor (26). Further work surveying healthcare professionals in Leyte would help clarify which of these scenarios is most likely.

In studies in other LMICs, women often cite health benefits of alcohol to promote lactation (14) and directly benefit young children when given to them. In our study, alcohol exposure extended beyond pregnancy with 15% of mothers giving their children tuba during their first year of life. Deworming was the reason most often cited for this practice. The frequency of this response suggests an underlying cultural belief that tuba contains antiparasitic properties, despite there being no evidence that alcohol exhibits antiparasitic effects *in vivo*. This belief may be tied to the significant burden of schistosomiasis, a disease caused by parasitic trematode worms, in the region (27).

All of the women surveyed (100%) stated that they would like to learn more about how to keep their pregnancy and baby healthy. Additionally, nearly all mothers (98%) reported that they would reduce their tuba or alcohol consumption if they were told that tuba or alcohol has been shown to have negative effects on them and their unborn child. Such high response rates highlight mothers' underlying desire to maintain healthy pregnancies as well as their willingness to modify their behavior with appropriate educational intervention. It also supports a key tenet of behavioral change, specifically motivation to change. When asked which modalities they would most like to learn from with regards to maternal-fetal health, all participants selected "talk with doctor during regular appointment," emphasizing one potential avenue of public health intervention. In this setting, other healthcare providers such as midwives would also need to be engaged as they provide a large proportion of prenatal care in Leyte.

There are currently few studies of KAPB regarding prenatal alcohol exposure in low- and middle-income countries (LMICs), such as The Philippines. The findings from this study may not be solely limited to the communities of Leyte; they likely apply more broadly to resource-poor settings throughout the world

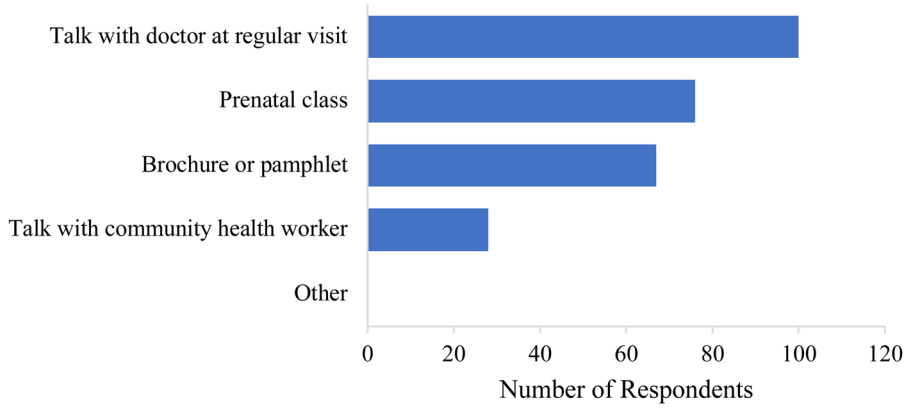

FIGURE 3
Preferred modalities by which participants would like to learn more about healthy pregnancies.

with cultures that have similar alcoholic beverages consumed prenatally. It has been well-documented that numerous cultures consume similar customary wines, notably during pregnancy. In India, an alcoholic palm wine known as toddy is consumed during pregnancy and has been shown in rat fetuses and pregnant rats to cause hyperlipidemia, hypoglycemia, and alcohol-related liver toxicity at rates above that of only ethanol consumption (28, 29). In the Bendel State of Nigeria, pregnant women consume a palm wine that is believed to increase lactation despite the general lack of knowledge of its alcohol content (30). These examples illustrate the need for a deeper understanding of the KAPB of pregnant women who consume various forms of alcohol, whether or not they are aware of the alcoholic nature of the beverages they drink. It also suggests that in resource-poor settings, the prevalence of largely unregulated "home brews" makes it more difficult to track consumption and provide formal warnings on labels. The study further supports the need for more focused public health and educational interventions related to prenatal alcohol consumption specific to resource-limited settings to ultimately to reduce FASD morbidity globally.

This study has some limitations. While a pilot study was performed to optimize comprehension and reliability, we did not conduct extensive test-retest reliability assessments. Although we adapted an already existing, validated survey in an attempt to improve validity, the initial instrument required extensive modification in order to meet literacy levels and to adequately capture the knowledge, attitudes, practices, and beliefs specific to our target population. Further, since this KAPB survey was conducted postnatally, we could not validate reported prenatal practices against a gold standard measure of current alcohol consumption such as PEth (phosphatidylethanol) testing (31). In addition, participants were surveyed anywhere from 6 months to 24 months postpartum, which may have impacted accuracy of responses regarding prenatal alcohol consumption practices, with women asked later perhaps having lower recollection of practices. Finally, response bias is always a possible concern when dealing with behaviors surrounding alcohol use, though such biases are more likely when there is potential stigma associated with a specific response (32). Such biases can lead to inaccurate estimations of alcohol consumption during pregnancy. This is less likely in the current study as prenatal tuba consumption does not appear to be highly stigmatized in Leyte based on both the high rates of reported use and the misconception that tuba does not contain alcohol.

The finding that most women believed tuba did not contain alcohol hindered interpretation of several questions which asked about "tuba or other alcoholic beverages." Participants may have found it difficult to comprehend questions which grouped tuba into the same category as alcoholic beverages. For example, nearly half (48%) of participants answered "True" to the statement: "Tuba or other alcoholic beverages are good for you and the baby while you are pregnant." Given that many participants did not regard tuba as an alcoholic beverage, it is difficult to assess whether participants were addressing tuba, alcoholic beverages, or both items in their answers. It should also be noted, however, that we split many analyses based on whether women believed tuba contained alcohol or not and it was still the case that 56% of women who believed tuba contained alcohol continued to drink tuba during pregnancy. In future studies, these should be separated.

Conclusion

Misinformation about tuba as an alcoholic beverage appears to play a role in the practices surrounding maternal and pediatric tuba consumption in Leyte, The Philippines. Most participants in our study reported consumption of alcohol during pregnancy. Of

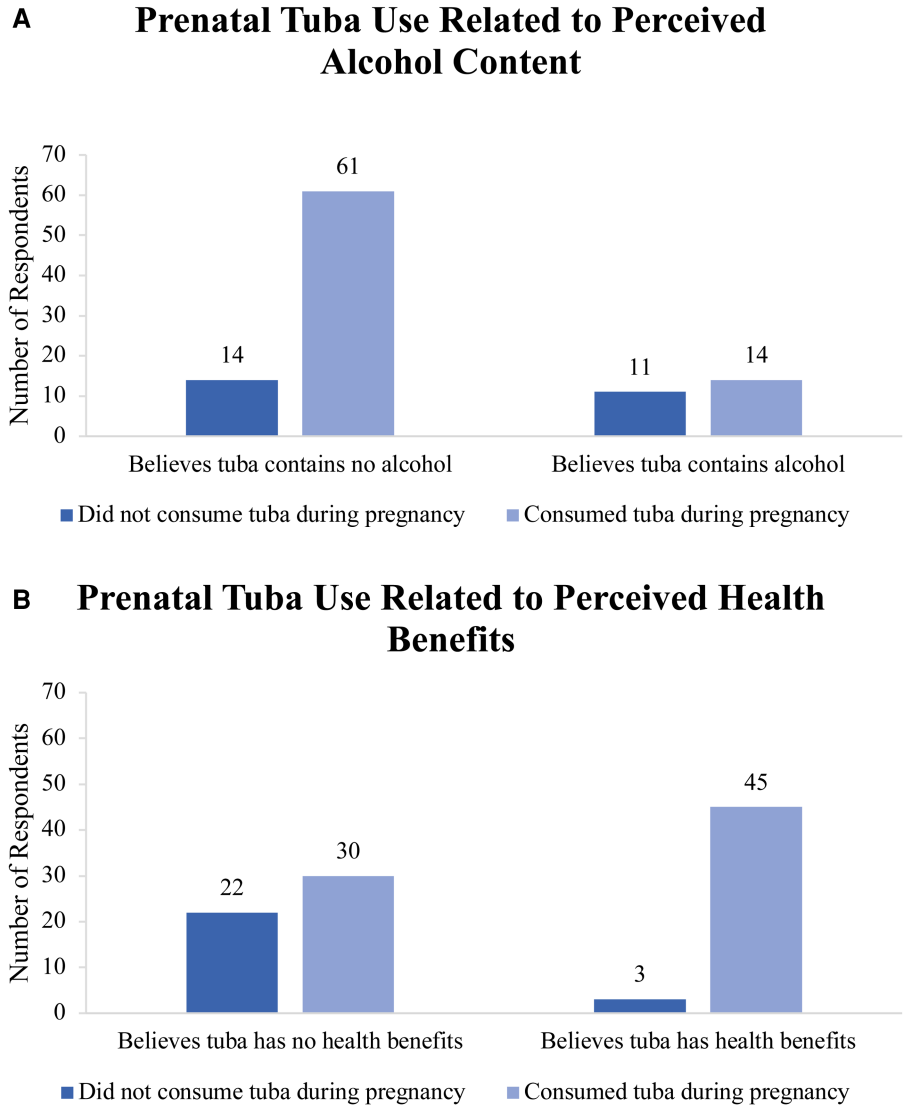

FIGURE 4
(A) Prenatal tuba use among participants as related to their perception of alcohol content in tuba. (B) Prenatal tuba use among participants as related to their perceived health benefits of tuba.

note, the majority of these mothers consumed exclusively tuba during their pregnancy and most of them did not acknowledge tuba to be an alcoholic beverage. This suggests key areas for education, especially since women stated they would change behaviors if doing so would improve the health of their babies. Given tuba's 7%–8% alcohol content and that there is no known safe threshold for alcohol consumption during pregnancy, the high rate of tuba consumption in our study highlights a serious risk of FASD in the offspring of the population surveyed and likely many populations globally that consume home brews. Future work should focus on incorporating tuba screening into already existing structures for alcohol and tobacco smoking screening at prenatal visits. Data from this study can inform local health departments in the creation of health education materials and/or programs addressing prenatal alcohol use for women of childbearing age.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by Rhode Island Hospital Institutional Review Board.

The patients/participants provided their written informed consent to participate in this study.

Author contributions

AH, MN, and JF developed the hypotheses and constructed the KAPB survey. MS, AM, EM, MJ, MU, and VT planned and led the field work. MN, AH, and SD analyzed the data and created the draft manuscript. All authors read, contributed to, and approved the final manuscript. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at https://www.frontiersin.org/articles/10.3389/fgwh.2023.1156681/full#supplementary-material

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Reducing the risk of prenatal alcohol exposure and FASD through social services: promising results from the FAR SEAS pilot project

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Introduction: Within FAR SEAS, a multi-component evidence-based community intervention was implemented and evaluated in Mazovia (Poland), with the aim of preventing alcohol-exposed pregnancies, and therefore preventing FASD.

Methods: Multi-disciplinary professionals from different services (social, addiction, and psychology), recruited women of child-bearing age (pregnant and not pregnant) in local communities, screened them for alcohol risk, and allocated participants (n = 441) to groups for low- (70%), moderate- (23%), or high-risk (7%) of alcohol exposed pregnancy, to provide interventions tailored to their needs. The non-parametric sign test, testing differences between pairs of observations before and after intervention was used to evaluate the outcomes.

Results: Follow-up data (collected from 93% of participants) indicated positive changes in the key outcome variables: risky alcohol consumption dropped by 81%, contraception use increased by 15% and visiting a gynecologist increased by 39%; as well as in associated psychosocial risk factors (decrease in cigarette and drug use, domestic violence and depressive symptoms). No changes were noted in frequency of other service use (medical, psychological, or social). The most prominent changes were observed in the moderate-risk group.

Discussion: Changing risky behaviors (alcohol consumption and sex without contraception) to prevent alcohol exposed pregnancies is feasible at the local level, even without engagement of medical professionals. Key challenges, related to engaging professionals and local authorities, must be addressed; and procedures should be adapted to local contexts and needs.

KEYWORDS

fetal alcohol spectrum disorder (FASD), prenatal alcohol exposure, prevention, intervention, local community

1. Introduction

Alcohol consumption during pregnancy may result in a series of adverse effects to the fetus including congenital anomalies and behavioral, cognitive and adaptive deficits, collectively known as Fetal Alcohol Spectrum Disorder (FASD). FASD is preventable by abstaining from drinking alcohol during pregnancy but effective prevention is complex and requires activities at various levels, targeting general population, women of childbearing age, women with alcohol problems and postpartum (1). For this reason, the EU strategy to support Member States in reducing alcohol related harm (2) re-quested governments to raise awareness of the risks of drinking during pregnancy, and stressed the need for evidence-based policies and practices to reduce alcohol related harms. In line with this statement, the European Commission awarded a service contract under the 2018 EU health program to deliver a project called FAR SEAS, with the aim of promoting European knowledge exchange, and piloting regional strategies to reduce FASD. The main objectives of FAR SEAS were to promote regionally implemented strategies to reduce and prevent fetal alcohol syndrome (FAS) and fetal alcohol spectrum disorder (FASD); and to facilitate knowledge-exchange and capacity-building among EU Member States. One of the key elements of the project was to test the implementation of a multi-component, evidence-based, community intervention aimed at preventing alcohol consumption among pregnant women and women in child-bearing age, through a regional-level pilot study.

The region chosen for the pilot was the Mazovian voivodeship in central Poland due to: relatively high prevalence of alcohol consumption reported by Polish pregnant women (from 15 to 39%, depending on the study) (3); significant FASD prevalence among Polish school students aged 7 to 9 years, in line with the estimated prevalence of FASD in the entire WHO European region (4) [the Polish prevalence is estimated to be higher than 20 cases per 1000; (5)].

The piloted program aimed to reduce the risk of prenatal alcohol exposure (PAE) in the general population of women of childbearing age. Specific objectives included:

- Reduction of risky alcohol consumption (among not pregnant women) and prevention of alcohol use among pregnant women;
- Increasing effective contraception use (among not pregnant women who drink alcohol), given that a high risk of fetal alcohol exposure is associated with unplanned pregnancy. Since a majority of women drink alcohol regularly (at least once a month), the likelihood that they will continue drinking until they find out they are pregnant is very high (6). Research indicates that about 30% of pregnancies in Poland are unplanned (7, 8);
- Increasing use of professional support to deal with complex psychological, medical and social challenges, which have been found to increase the risk of alcohol use during pregnancy.

Based on the literature review and consultation of Polish experts in the FAR SEAS project, depression was selected as one of the key factors to be addressed. The lifetime prevalence of depression among Polish women from 18 to 49 years of age is 4% (9). Systematic reviews have shown that about 10% of pregnant women and 13% of those who have given birth experience some type of mental disorder, most commonly depression or anxiety (10, 11). Although the estimates of the prevalence of depression during pregnancy vary widely, ranging from 0.5 to 51%, rates of depression, especially during the second and third trimesters of pregnancy, are substantial (12). Moreover, women with depression have shown greater difficulty in changing their behavior and reducing alcohol consumption during pregnancy than women without depression (13).

Intimate partner violence is another factor associated with a higher risk of alcohol consumption during pregnancy (14–17). Research showed that 27% of women in Poland experienced domestic violence at least once (18). Women who experience violence live in unpredictable, hard-to-control and difficult to manage environments, which may impede their efforts to reduce drinking and practice birth control. They may also be at higher risk of using alcohol and other substances to self-medicate or cope with the unbearable situation (19).

The third risk factor taken into account in the FAR SEAS project is the use of other psychoactive substances, i.e., tobacco and illicit drugs (20). The prevalence of current tobacco smokers among Polish women of age 15 + is 17%, e-cigarettes smokers is 4% (21), lifetime prevalence of any drug among women from 18 to 64 years of age is 10% (the most popular illegal substances is marijuana and hashish, i.e., cannabis products –8% of surveyed women) (22). About 40% of women who drank alcohol during pregnancy also used at least one other psychoactive substance–most commonly tobacco and marijuana (23). Polydrug use during pregnancy may increase negative pregnancy outcomes and health problems for the child (24–27).

2. Materials and methods

The pilot methodology was based on Participatory Action Research (PAR) (28–31)—in order to build an understanding of the complexities of FASD prevention at the local and regional level, and to facilitate and evaluate community-based activities (empowering and activating local stakeholders, recruiting service providers, communication strategy, etc.). This approach facilitates capacity building in a community to promote health and solve problems; and acknowledges the fact that local knowledge is essential to achieve an accurate understanding of local problems, and to design the most adequate measures.

The general overview of the pilot project activities is presented on the flow chart (**Figure 1**) and described in details below. The local community multi-professional teams were recruited and trained in Spring 2021. Recruitment of the participating women took place between June and December 2021 and the follow up data collection from January to July 2022.

The study was conducted in accordance with the Declaration of Helsinki, and approved by the Ethics Committee of State Agency for Prevention of Alcohol Related Problems (Poland). Informed consents were obtained from all subjects involved in the study (from local professionals and participants).

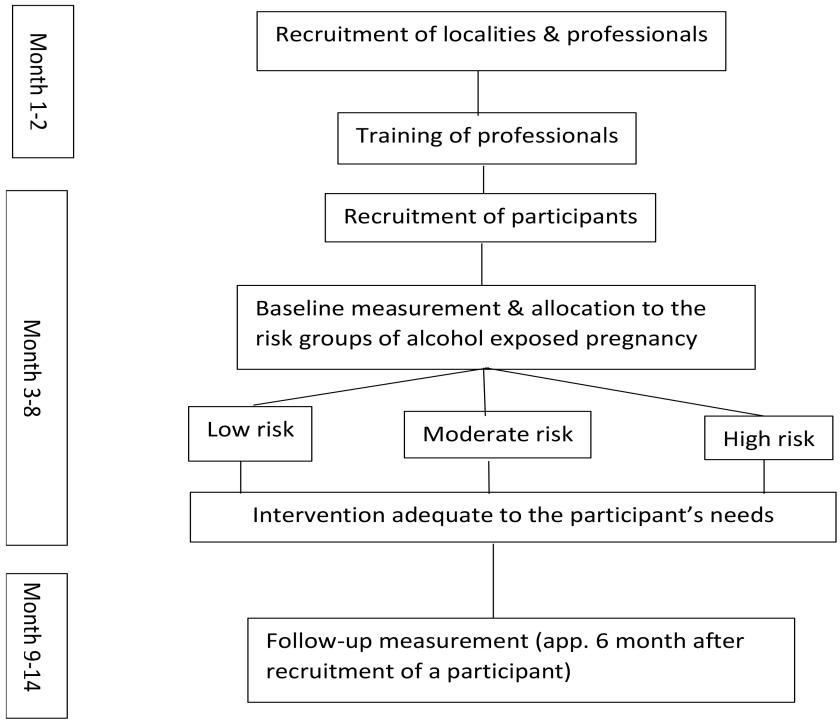

FIGURE 1
The flow chart of the pilot project.

2.1. Target population

Females from 15 to 49 years of age were eligible to participate, whether pregnant or not pregnant, but without recognized infertility. Several entry points were planned to reach different groups of participants:

- Primary Health Care Units (PHCU)—for women of childbearing age (including pregnant women) coming for a routine visit.
- Gynecological centers–for women visiting gynecologists/obstetricians for checkups or at the beginning of pregnancy.
- Public mental health centers—for women with mental health disorders.
- Addiction treatment centers—for women with alcohol or drug use problems.
- Social Service Centers—for women with alcohol problems and/or psychosocial risk factors, as well as women whose children are at risk of being taken into foster care because of their mothers' alcohol problems.
- Special centers for youth with behavioral disorders—for girls and young women (aged 15 +) who are at risk of unplanned teenage pregnancy.
- NGOs/Abstinence organizations—for women who either have/had alcohol problems themselves, or who live in families with alcohol-related problems.

In line with the PAR approach (28–31), a non-probabilistic sampling method was applied participants. The local staff (service providers) guided by the FAR SEAS training, were encouraged to invite all women in childbearing age (15–49 years old) they were in touch with via any of the entry points mentioned above. The invitation to the project included providing information about the project (orally and by written form) and obtaining informed consent to participate.

In practice, the local specialists had a freedom in selecting the project participants. Qualitative data collected *post hoc* indicated that they adopted different strategies–some limited recruitment to their clients, and others–actively sought participants, also using their non-professional contacts in family and among friends. This flexible procedure was chosen as the most realistic and feasible approach, taking into account variability of local contexts, recruiting professionals, and entry points in the pilot project, as well as the difficulties in accessing the study target population.

2.2. Professionals

The intention of FAR SEAS was to create five independent multi-professional teams to work in the five communities within the region. As each local context is slightly different, with established leaders occupying a variety of roles, the first and vital step in creating the new local interdisciplinary teams was to invite representatives of local authorities to cooperate with the project, in order to identify key local institutions, and specialists who could form a team. After getting the service managers and planners on board, representatives from Primary Health Care (PHC), gynecology/obstetric centers, social services, mental health,

addiction centers and other professions were invited to join each of the local teams. Their tasks included:

- Recruitment of participants;
- Collecting baseline data and assigning women to the appropriate intervention group (low, moderate, or high risk of alcohol exposed pregnancy);
- Providing services adequate to the allocation and/or referring participants to another specialist within the local team;
- Follow-up assessment of participants (approximately 6 months after recruitment).

Remuneration was offered to the providers for each activity within the project.

2.3. Training

All professionals were invited to participate in the online training aimed at building capacity to work within the local interdisciplinary team in the FAR SEAS pilot. The topics of the 7-h training course included: Risks and consequences of the consumption of alcohol and other drugs during pregnancy; skills and tools to address and prevent alcohol-related harm in pregnant and child-bearing age women; common understanding of the work to be done, data collection coordination and good cooperation and referral pathways within the local team. Volunteering staff members had the opportunity to attend additional training (11 h) on motivational interviewing (MI) and the CHOICES program (31–33) aimed at preparing individuals to work with participants with moderate or high risk of alcohol exposed pregnancy.

2.4. Measures

After giving informed consent to participate in the project, participants were invited to have a structured computer assisted personal interview (CAPI) to determine their current pregnancy status (yes/no/trying to get pregnant), socio-demographic characteristics (age, education, work, family, and housing situation) and risk factors for alcohol use during pregnancy. The interview lasted approximately 20–30 min and no compensation was offered for baseline and follow up assessments, nor for the participation in interventions.

For women who were not pregnant, these risk factors included: (1) Risky alcohol consumption—measured with the AUDIT-*C*-test (34) and cut-off point 4. Where the score was 4+, the entire AUDIT test (35) was applied; and (2) Contraception use in the past 3 months—measured with two questions: (1) "Are you sexually active?" and if yes, and (2) "What contraceptive method do you normally use?" with a range of options [None, Condoms, Birth Control Pills, Vaginal Ring (NuvaRing), Contraceptive patch, Emergency Contraception (e.g., morning-after pill), Contraceptive progestin injection (medroxyprogesterone acetate/e.g., Depo-Provera Shot), IUD (intrauterine devices/coil), Birth control implant (e.g., Implanon, Nexplanon), Other]. The answers were dichotomized into "no" and "yes" use of contraception and sexually non-active participants were excluded from analysis.

Women who were pregnant at the time of recruitment, were asked the AUDIT-C questions first, in reference to the last 3 month before getting pregnant; and, then, the same questions but on the period during pregnancy. Score of 4+ before pregnancy was interpreted as a risk factor for alcohol use at least in the first trimester, and any alcohol use during pregnancy was an indicator of risk.

All participants were asked about current use of (a) cigarettes and (b) other drugs (psychoactive substances, sedatives or sleeping pills). Women who were not pregnant could choose one of four answers (Never used; I used to use it, but now I don't use it; I use occasionally; I use regularly). Pregnant women had two more options: I used to smoke, but now I do not smoke because of the pregnancy; I have reduced smoking since being pregnant.

Psychosocial risk factors included depressive symptoms measured with the PHQ-9 (36–38). Moderate or higher severity of symptoms (score 10 +) was interpreted as the risk factor. Screening for domestic violence was based on the questionnaire "Assessment of the family situation in terms of violence" (39), and a positive answer to any of the 9 questions asking about different forms of physical, psychological or economical violence (e.g., "Has your partner or someone close to you ever behaved this way toward you?": "pushed, tugged, pulled hair"; "humiliated/criticized"), was taken as an indicator of risk.

The use of services was measured with one question: "In the last 3 months, have you had any advice/consultation with a GP/nurse, gynecologist/midwife, Social worker, Addiction therapist, Psychologist/psychiatrist?" For each specialist the respondent indicated never, 1–2 times or 3 times or more.

The same questions were asked in the follow-up session approximately 6 months after recruitment. Alcohol, contraception, and service-use were the key outcome measures, and psychosocial risk factors (cigarette and drug use, depressiveness and domestic violence)—secondary outcomes.

2.5. Allocation to the risk group and interventions

Based on the screening results, participants were allocated to a low-, moderate- or high-risk group for risk of having a baby with FASD (**Table 1**). To do this, the local staff member(s) were instructed to follow the criteria:

1. Low risk means: (a) if a participant is pregnant—abstinent since before pregnancy OR before pregnancy used to drink moderately (AUDIT-C score <4) and stopped drinking as soon as she learned about pregnancy; and (b) if not pregnant—no hazardous drinking and use of contraceptive measures.
2. Moderate risk means: (a) if a participant is pregnant—risky alcohol consumption (AUDIT-C score 4 +) in the past (before pregnancy) AND/OR presence of significant psychosocial risk factors (depressiveness and/or violence, and/or economic challenges, and/or use of drugs); and (b) if not pregnant—risky alcohol consumption AND/OR psychosocial risk factors including no use of contraceptive measures.

TABLE 1 Risk groups allocation criteria.

Level of risk	Not pregnant	Pregnant
Low	AUDIT C < 4 and no PSR[1]	No drinking[2] and no PSR
Moderate	AUDIT C ≥ 4 and no PSR or AUDIT C < 4 and PSR positive	Drinking and no PSR or No drinking and PSR positive
High	AUDIT C ≥ 4 and PSR positive or AUD (AUDIT ≥ 7)	Drinking

[1]PSR = Psychosocial risks.
[2]No drinking = A woman is an abstinent or drank moderately before pregnancy and stopped drinking as soon as she planned pregnancy or learned about pregnancy.

3. High risk means: (a) if a participant is pregnant—current alcohol use; and (b) if not pregnant—alcohol use disorders.

Despite the outcome according to these guiding criteria, the final decision about allocation and the intervention offered to the individual client, was always made by the local team member(s) based on their professional experience and any additional information they might have (e.g., from the contacts with a client prior to the FAR SEAS project).

The local teams were encouraged to follow up the screening by offering the intervention adequate to a client's needs (1):

- To participants at low risk of alcohol exposed pregnancy—brief feedback to support their attitude and underline the importance of alcohol abstinence during pregnancy.
- To those in the moderate-risk group—activities providing the opportunity for safe discussion about reproductive health, contraception, pregnancy, alcohol use and related issues in a form of brief intervention (40, 41) and/or 1 to 4 individual motivational sessions (according to the client needs) aimed at changing at least one of the risky behaviors: alcohol use and/or sex without contraception [based on: Project CHOICES (31–33)].
- To those in the high-risk group–who need special support to deal and cope with their individual risk factors that make them especially vulnerable for giving birth to a child with FASD—supportive, specialized services, i.e., individual motivational sessions and/or referral to specialists in addiction therapy, psychotherapy, medicine etc., according to individual needs.

Typically, the interventions were provided in the same setting in which a participant was recruited, except for visits in a participant's home. No compensations on retention in the project was offered to participants.

The intervention period started immediately after the recruitment of a participant. Usually, the first step, was to provide feedback on the screening results and, in the case of women from the low risk group—it was often the sole form of intervention. If more intensive measures were needed, the intervention period could be extended to a maximum of 6 months, although it usually lasted about 2–3 months, depending on the type of services and the availability of the participant. For example, some participants did not immediately decide to participate in sessions based on the CHOICES project, or returned after a longer absence for a referral to a specialist.

In general, interventions that the local specialists proposed to the participants covered the full spectrum of possibilities provided for in the project (Figure 2). For women from the moderate risk group, the next step (after feedback) was a brief intervention (in most cases—covering two meetings 1 or 2 weeks apart) or motivational interview sessions aimed at reducing risky drinking and/or encouraging use of contraception. In average the number of motivational sessions based on the CHOICES approach for one participant was 1.9 but, as the final decision about the extent of the support needed by a particular participant was made individually by a local specialist, in two cases of women at high-risk of PAE, support was extended to 5 and 6, compared to 4 sessions initially planned.

Individualized support plans were developed for n = 170 women including, individual motivational sessions and referrals to specialists (psychologist, gynecologist, midwife, addiction therapist, and others). The individualized offer for 5 participants also included home visits.

2.6. Data analysis

Analyses were performed using IBM SPSS Statistics 28.0. In case of the continuous variable—participants' age, the F-test was adopted to make cross-group comparisons. All other data were presented as frequencies (Freq) for categorical variables, and the chi-squared test was adopted for comparisons between groups. The evaluation of improvements in desired outcomes was based on the non-parametric sign test, testing differences between pairs of observations before and after intervention. The sizes of groups with positive values at baseline and follow-up were compared in the entire sample, and in the sub-groups differentiated by the level of risk of having a baby with FASD. In all tests, a p-value of <0.05 was considered statistically significant. To illustrate and facilitate interpretation of the statistically significant results, the coefficients of variation between measures were calculated according to the formula:

$$Freq\left(follow\ up\right) - Freq\left(baseline\right)]/Freq\left(baseline\right) * 100.$$

3. Results

3.1. Characteristics of professionals

Initially, 30 specialists from 5 different sites–two towns (Płock, and Radom) and 3 districts of Warsaw City–agreed to participate in the project. Teams from two of the Warsaw districts withdrew from the project just before or immediately after the initial training. Therefore, an additional team (5 professionals: 2 social workers, 1 psychologist, 1 pedagogue, 1 addiction therapist) from another town–Pruszków–was recruited. In the end, 31 professionals participated in the initial training and 25 of these undertook project activities. Most of them were social workers and/or family assistants–providing practical support to the family in consultation with the social worker (42) (4 in Plock, 3 in Radom,

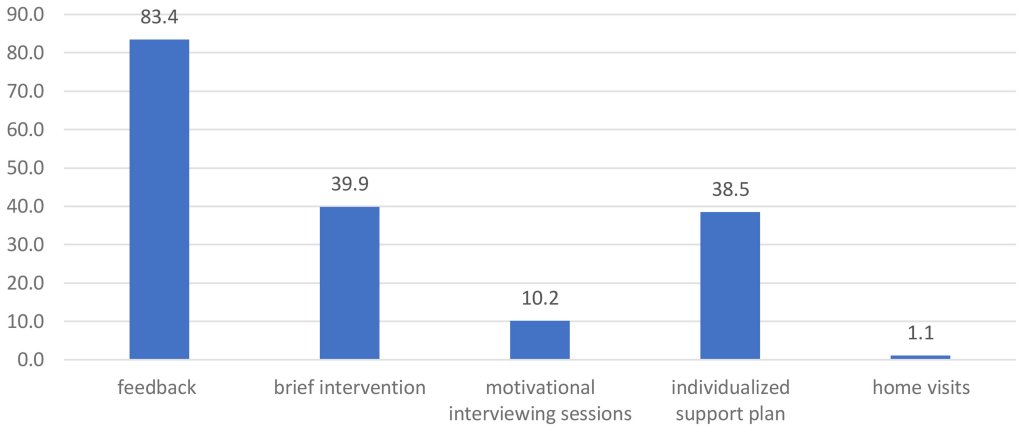

FIGURE 2
The percentage of participants (n = 441) who received a given form of intervention within the project.

TABLE 2 Recruitment of participants and their allocation to alcohol exposed pregnancy risk group by the entry site location.

	The risk of alcohol exposed pregnancy (n)				All (n)	Pregnant women (n)
Location	Low	Moderate	High	Not assessed		
Warsaw-Ursus	1	1	0	2	4	1
Płock	196	69	7	0	272	23
Radom	98	28	23	1	150	10
Pruszków	12	2	1	0	15	8
All	307	100	31	3	441	42
%	69.61%	22.68%	7.03%	0.06%	100%	9.52%

2 in Ursus). All local teams included at least one psychologist (2 in Radom) and one addiction therapist. The Płock team included also the pedagogue and the member of the abstainers' association. No one medical doctor was involved in any of the teams but in Radom one midwife and in Płock one nurse/midwife was engaged.

3.2. Characteristics of participants

The final sample consisted of N = 441 women recruited into the project by local staff. The majority of participants were recruited via social services (77.3%), followed by addiction therapy (5.7%) and health care facilities (2.5%). All other participants (14.5%) were recruited via personal contacts of local staff members (all profiles) or NGOs. Among the recruited participants, 9.5% (N = 42) were pregnant at the time of recruitment.

The majority of participants were recruited in Płock (61.7%), followed by Radom (34%). After screening, 69.6% of the total sample were allocated to the low-risk group (N = 307); 22.67% to the moderate-risk group (N = 100); and to the high-risk group 7% (N = 31) (Table 2).

The mean age of participating women was 33 years (SD = 8.46), ranging from 16 to 49 years (2 participants were underage—16 and 17 years old). Regarding other socio-demographic characteristics: almost half of the sample were married or in a constant relationship (49%); 75% had secondary or higher education; and over 60% were employed. Significant differences in terms of socio-demographic features between risk groups have been noted (Table 3): in mean age (the low-risk group being significantly older); occupational status (employment rate decreased with group risk); marital and living status (constant relationships and living with a husband/partner and a child/children were most prevalent in low-risk group).

As expected, given the allocation process, the prevalence of psychosocial factors increasing the risk of alcohol use during pregnancy (being a victim of domestic violence, elevated risk of depression, psychoactive substance use, and risky drinking when not pregnant) were the lowest in the low-risk group and the highest in the high-risk group. The only risk factor for which the statistical test of inter-group differences did not reach the significance level was the use of contraceptive measures. Across all groups, nearly half of the participants (46.9%) did not use contraception.

3.3. Follow-up results

At follow up, data were collected from 411 participants (93.2% of the sample).

Among the 42 women who were pregnant at the time of the recruitment, n = 5 reported risky alcohol consumption before pregnancy and n = 3 reported any alcohol use during pregnancy (Table 3). None of the n = 7 women who were still pregnant at

TABLE 3 Baseline characteristics of participants by their allocation to alcohol exposed pregnancy risk group.

	Low risk (n = 307)	Moderate risk (n = 100)	High risk (n = 31)	p
Mean age (range)	34.10 (16–49)	31.57 (18–49)	30.87 (17–43)	0.008[1]
Education				
Primary	11.1%	13.6%	29.0%	0.118[2]
Vocational	9.5%	13.6%	9.7%	
Secondary	37.0%	41.7%	35.5%	
Tertiary	41.3%	30.1%	25.8%	
Occupational status				
Employed	66.2%	51.5%	38.7%	<0.001
Student	16.8%	25.0%	11.8%	0.369
Unemployed	41.6%	33.3%	58.8%	
Health problems	9.9%	10.4%	17.6%	
Child care	31.7%	31.3%	11.8%	
Marital status				
Married/constant relationship	56.7%	36.9%	22.6%	0.002
Single	28.9%	46.6%	51.6%	
Divorced/separation	12.5%	14.6%	22.6%	
Widow	1.3%	1.9%	3.2%	
Living with . . .				
Alone	4.9%	1.9%	9.7%	<0.001
Partner/husband and children	43.6%	27.2%	22.6%	
Partner/husband	19.7%	21.4%	9.7%	
Other relatives	12.1%	28.2%	35.5%	
A child/children	15.7%	19.4%	12.9%	
Other	3.9%	1.9%	9.7%	
Psychosocial risk factors				
Domestic violence	5.4%	12.6%	38.7%	<0.001
Depressive symptoms	1.7%	13.5%	39.3%	<0.001
Current cigarette use	26.1%	65.3%	86.2%	<0.001
Current drug use	1.6%	7.8%	19.4%	<0.001
Not pregnant:				
No contraception use (not pregnant)	42.9%	54.3%	60.0%	0.067
Risky alcohol use (not pregnant)	1.1%	20.4%	63.0%	<0.001
Pregnant when recruited	N = 29	N = 9	N = 4	
Risky alcohol use before pregnancy	N = 0	N = 1	N = 4	
Any alcohol use during pregnancy	N = 1	N = 2	N = 1	

[1] F-test.
[2] Here and in the following columns chi square test was used.

the time of the follow-up measurement drank alcoholic beverages. These differences were not tested statistically.

In the entire sample of not pregnant women, self-reported risky alcohol consumption dropped at follow-up after 6 months indicating the coefficient of variation = −81.25, and contraception use increased by 15 percentage points (Table 4).

Changes in all other risk factors were assessed in the entire sample (regardless of the pregnancy status at the time of recruitment). Positive outcomes (decreases) were observed for all psychosocial risk factors: current cigarette and drug use, domestic violence, and depressive symptoms. No changes occurred in the frequency of visits to specialists, except for visiting a gynecologist, which increased by 39.19 percentage points (Table 4).

The analysis of changes in FASD risk factors in the low-risk group of participants (Table 5) indicated a significant increase in contraception use and visits to a gynecologist (by 9.49 and 32.14

TABLE 4 Changes in the risk factors of FASD in a child between the baseline and the follow-up, assessed with the sign test (entire sample).

		N	*p*	Coefficient of variance
Risky alcohol use	Positive change[1]	53	<0.001	−81.25
	Negative change	1		
	No change	314		
Contraception use	Negative change	12	<0.001	14.59
	Positive change[2]	39		
	No change	295		
Current cigarette use	Positive change[3]	35	<0.001	−18.99
	Negative change	5		
	No change	369		
Current drug use	Positive change[4]	14	0.004	−63.16
	Negative change	2		
	No change	397		
Domestic violence	Positive change[5]	25	<0.001	−100
	Negative change	0		
	No change	376		
Depressive symptoms	Positive change[6]	80	0.012	−53.57
	Negative change	18		
	No change	306		
Consultation with a GP/nurse	Negative change	76	0.750	
	Positive change[7]	81		
	No change	246		
Consultation with a gynecologist	Negative change	57	<0.001	39.19
	Positive change[7]	105		
	No change	242		
Consultation with a social worker	Negative change	33	0.903	
	Positive change[7]	35		
	No change	328		
Consultation with an addiction therapist	Negative change	9	0.607	
	Positive change[7]	6		
	No change	383		
Consultation with a psychologist/psychiatrist	Negative change	25	1.000	
	Positive change[7]	24		
	No change	346		

[1]Follow up risky alcohol use <Baseline risky alcohol use.
[2]Follow up contraception use >Baseline contraception use.
[3]Follow up cigarette use <Baseline cigarette use.
[4]Follow up drug use <Baseline drug use.
[5]Follow up domestic violence <Baseline domestic violence.
[6]Follow up depressive symptoms <Baseline depressive symptoms.
[7]Follow up consultations with a specialist >Baseline consultations with a specialist.

percentage point, respectively). At the same time, the number of current cigarette smokers decreased in this group by 22.22 percentage points.

In the moderate-risk group, significant changes occurred in all outcome variables in the desired direction (Table 6).

In the high-risk group, risky alcohol consumption dropped by 61.11 percentage points, depressive symptoms by 63.64, and domestic violence by 100 (Table 7).

No negative effects of the interventions were noted in any of the sub-groups, nor in the sample as a whole.

TABLE 5 Changes in the risk factors of FASD in a child between the baseline and the follow-up in the low-risk group, assessed with the sign test.

		N	*p*	Coefficient of variance
Risky alcohol use	Positive change[1]	7	0.070	
	Negative change	1		
	No change	247		
Contraception use	Negative change	10	0.037	9.49
	Positive change[2]	23		
	No change	204		
Current cigarette use	Positive change[3]	19	<0.001	−22.22
	Negative change	3		
	No change	264		
Current drug use	Positive change[4]	3	0.625	
	Negative change	1		
	No change	285		
Domestic violence	Positive change[5]	5	0.063	
	Negative change	0		
	No change	272		
Depressive symptoms	Positive change[6]	5	0.774	
	Negative change	7		
	No change	268		
Consultation with a gynecologist	Negative change	44	0.015	32.14
	Positive change[7]	71		
	No change	170		

[1]Follow up risky alcohol use <Baseline risky alcohol use.
[2]Follow up contraception use >Baseline contraception use.
[3]Follow up cigarette use <Baseline cigarette use.
[4]Follow up drug use <Baseline drug use.
[5]Follow up domestic violence <Baseline domestic violence.
[6]Follow up depressive symptoms <Baseline depressive symptoms.
[7]Follow up consultations with a specialist >Baseline consultations with a specialist.

4. Discussion

The evaluation showed positive results of the interventions conducted in terms of the change in the key targeted behavior, i.e., a reduction in the percentage of women who drink alcohol in a risky manner. Significant decrease in psychosocial risk factors (current cigarette and drug use, depressiveness, and reporting domestic violence) were also observed. Positive changes were also noted, but on a smaller scale, in terms of the increasing percentage of women using contraception and visiting specialists in gynecology.

These positive results were obtained in spite of the COVID-19 pandemic restrictions introduced in Poland in 2020 and unprecedented conditions of health work at that time. Due to the COVID-19 pandemic, health professionals in particular were overstretched and limited their work with patients to telephone counseling. It is likely that this was one of the main reasons for the low levels of medical professionals participating. But, as indicated the unofficial recruitment talks, there were also other barriers, such as, e.g., those reported in the Danish study (43): poor confidence in navigating between health and social care systems, fear of breaking the professional-patient alliance when touching the alcohol consumption issues in antenatal care or reporting to the social services.

An absence or scarcity of medical professionals in the local teams created additional challenges for the other professionals active in the project. However, the positive outcomes of evaluation indicate that the implementation of FASD prevention initiatives by professionals in the social care system, among others, is feasible and can be effective. This conclusion from our study seems particularly important and interesting due to the limited number of publications on the activities of social workers in the area of preventing alcohol consumption during pregnancy. Studies on the effectiveness of brief interventions or counseling are usually conducted in healthcare settings (44, 45). The community approach is applied only to work in the case management paradigm, with women proven to be at high risk for drinking during pregnancy (46, 47). Social workers' role is discussed, either as an element of much broader multi sectoral system approach (48, 49) or as recipients of professional trainings (50, 51).

Although our project is a pilot–focused on feasibility, process, and reaching different groups, rather than focusing purely on the effectiveness of a single prescriptive approach (52, 53), it

TABLE 6 Changes in the risk factors of FASD in a child between the baseline and the follow-up in the moderate-risk group, assessed with the sign test.

		N	*p*	Coefficient of variance
Risky alcohol use	Positive change[1]	35	<0.001	−94.59
	Negative change	0		
	No change	55		
Contraception use	Negative change	1	0.006	25.00
	Positive change[2]	11		
	No change	76		
Current cigarette use	Positive change[3]	13	0.007	−17.46
	Negative change	2		
	No change	82		
Current drug use	Positive change[4]	6	0.031	−75.00
	Negative change	0		
	No change	92		
Domestic violence	Positive change[5]	10	0.002	−100.00
	Negative change	0		
	No change	88		
Depressive symptoms	Positive change[6]	11	0.006	−83.33
	Negative change	1		
	No change	80		
Consultation with a gynecologist	Negative change	9	0.007	64.29
	Positive change[7]	26		
	No change	58		

[1]Follow up risky alcohol use <Baseline risky alcohol use.
[2]Follow up contraception use >Baseline contraception use.
[3]Follow up cigarette use <Baseline cigarette use.
[4]Follow up drug use <Baseline drug use.
[5]Follow up domestic violence <Baseline domestic violence.
[6]Follow up depressive symptoms <Baseline depressive symptoms.
[7]Follow up consultations with a specialist >Baseline consultations with a specialist.

provides the impetus for further exploration of the outcomes of FASD preventive interventions by social workers. In particular, it is notable that the professionals in our pilot project had considerable freedom of action, as indicated by fact that they made decisions on the scope of intervention for individual participants on their own or after consultations with other members of the local team. These decisions concerned, for example, the number of individual motivational sessions to conduct with each woman. The American experience of the CHOICES program shows that, depending on the individual recipient, working with 1, 2, or 4 sessions may be effective (31–33). Because our specialists worked with very different women (pregnant and not pregnant; occasional, risky or problem drinkers; with or without other psychosocial problems), they independently decided how many sessions to conduct in a given case. This highly individualized, tailored approach was probably one of the biggest strengths of the FAR SEAS project pilot, in line with the recommendations from the systematic review of FASD prevention programs (54). It could be concluded that the FAR SEAS pilot study tested the scale-up of a new flexible intervention approach, addressed at a broad target group of women, but tailored to the different women's characteristics and situations.

The specific profiles of the intervention teams, relying largely on social workers, also determined the profile of participants reached, among which there were few pregnant women. On the other hand, the rate of people at higher risk of drinking alcohol during pregnancy in our sample (30% classified to moderate and high risk groups) was higher than in the general population [based on the data indicating that 22% of women of child bearing age in Poland have had at least one Risky Single Occasion Drinking—RSOD episode in the past 12 months (55)].

The small number of pregnant participants in the study does not allow conclusions to be drawn on the effectiveness of the FAR SEAS approach during pregnancy specifically (even in a situation where we did not record any cases of alcohol consumption among participants who were pregnant at the time of last study visit). However, our findings do suggest positive influences of the interventions on the participants taken as a whole, especially those who drink alcohol at risky level and/or present other psycho-social risk factors of drinking alcohol during pregnancy, and therefore at higher risk of giving birth to a child with FASD (i.e., our moderate-risk group).

TABLE 7 Changes in the risk factors of FASD in a child between the baseline and the follow-up in the high-risk group, assessed with the sign test.

		N	*p*	Coefficient of variance
Risky alcohol use	Positive change[1]	11	<0.001	−61.11
	Negative change	0		
	No change	12		
Contraception use	Negative change	1	0.219	
	Positive change[2]	5		
	No change	15		
Current cigarette use	Positive change[3]	3	0.250	
	Negative change	0		
	No change	23		
Current drug use	Positive change[4]	5	0.219	
	Negative change	1		
	No change	20		
Domestic violence	Positive change[5]	10	0.002	−100.00
	Negative change	0		
	No change	16		
Depressive symptoms	Positive change[6]	7	0.016	−63.64
	Negative change	0		
	No change	19		
Consultation with a gynecologist	Negative change	4	0.388	
	Positive change[7]	8		
	No change	14		

[1]Follow up risky alcohol use <Baseline risky alcohol use.
[2]Follow up contraception use >Baseline contraception use.
[3]Follow up cigarette use <Baseline cigarette use.
[4]Follow up drug use <Baseline drug use.
[5]Follow up domestic violence <Baseline domestic violence.
[6]Follow up depressive symptoms <Baseline depressive symptoms.
[7]Follow up consultations with a specialist >Baseline consultations with a specialist.

Given the importance of being able to target the intervention to the group most in need of support, i.e., women most at high risk of alcohol exposed pregnancy, the result indicating significant reductions in risky alcohol consumption among the high-risk subgroup is very promising. It is also important that the interventions offered to this group within the FAR SEAS project had positive effects on their domestic situation (reduced violence) and mood (depressive symptoms). However, more intensive or different interventions, or the engagement of other specialists (probably, linking to health professionals) are needed to improve their reproductive health (i.e., contraception use, visiting a gynecologist), and to reduce other psychoactive substance use in pregnancy.

The improvement of some health behaviors (use of contraceptive measures, visits to a gynecologist, reduced cigarette smoking) in the low-risk group, suggests a need for basic health education for the general Polish population, especially among women in childbearing age.

The applicability of the study results to different populations and contexts may be limited by the uneven spread of participants across the different geographical and urban sites. An unstable social and medical situation at the time of the study made the recruitment of local stakeholders and individual specialists very difficult. Out of the six local teams that signed up for the project, only 4 teams were active, including 2 which were active only at a minimal level. In two other locations of the project (Płock and Radom), interdisciplinary teams of specialists (social workers, psychologists, addiction therapists, midwifes) were established to implement all the planned activities. Both highly active teams were led by people evidently well predisposed to this role: engaged, well organized, oriented to problem-solving and communicative (56, 57). In Radom the leader from social service center was appointed by the local authorities, while in Płock—one of social workers volunteered to this role. These teams managed to recruit and attend over 400 participants, the vast majority (93%) of whom also took part in the final measurement, which is a strength of the current data set. It is possible that a lack of good coordination and leadership was one of the reasons for the limited uptake and success of the pilot in the two other teams.

One other limitation of the study, which is encountered in many alcohol prevention interventions, is the reliance on self-reported data for alcohol use, which may result in a social desirability bias (which we can expect to be especially present

among pregnant women in the follow-up sessions). In addition, the freedom of local staff in selecting the project participants, although reflecting natural context of their work, may be considered a limitation of the study. It is possible that, consciously or subconsciously, they introduced a bias by inviting women they feel they can more easily work with, who may not be those most in need of the intervention. This indicates the need of more rigorous training and enforcement of research experiment standards in future studies.

5. Conclusion

The positive results of the pilot project indicate the feasibility and validity of implementing multi-center regional FASD prevention through inter-disciplinary teams at the community level. The most prominent changes in the prevalence of risky alcohol consumption were observed in the moderate risk group indicating potentially high returns on investment of addressing FASD prevention and interventions to this group; which should not be overlooked, despite the priority of focusing on women at high risk of alcohol exposed pregnancies. The results suggest an opportunity to build on the receptivity of women in the moderate risk group to prevention and advice, and that delivering timely interventions may prevent women from developing more risky behaviors leading to alcohol exposed pregnancies. Dissemination of FASD prevention at the local level requires the involvement of local authorities and directors of key institutions and coordinated work in a multidisciplinary team, which is one of the key facilitators of good implementation and sustainability of FAS/FASD prevention.

The main learning points and findings from the FAR SEAS pilot study have been fed forward into the FAR SEAS Guidance, which comprises 22 evidence-based recommendations, validated through international expert consensus, aimed at reducing alcohol consumption in women of childbearing age, particularly in pregnant women.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The study involving humans was approved by the Ethics Committee of State Agency for Prevention of Alcohol Related Problems (Poland). The study was conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation in this study was provided by the participants' legal guardians/next of kin.

Author contributions

KO-K, LS-G, FB, CG, and ES contributed to conception and design of the study. KO-K and MZ-S organized the database. KO-K, SG, and MZ-S performed the statistical analysis. KO-K, FB, LS-G, and CB wrote the first draft of the manuscript and sections of the manuscript. FB, SM, KO-K, and LS-G supervised the project implementation. FB and SM administered the project. FB, SM, and KO-K acquired funding for the project. All authors contributed to manuscript revision, read, and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Pilot study of attentional retraining for postpartum smoking relapse

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Introduction: Tobacco smoking is a leading cause of preventable death worldwide. The perinatal period provides a unique opportunity for intervention, as many smokers quit smoking during pregnancy but relapse postpartum. Novel relapse prevention interventions that reduce the burden of treatment attendance in this population are needed. Attentional retraining (AR) has been shown to reduce attentional biases toward smoking-related stimuli, a cognitive process implicated in smoking, AR has not been applied to perinatal smokers, and the effect of AR on craving and smoking is not clear. The goal of this study was to evaluate the delivery of AR for smoking cues in perinatal smokers utilizing a mobile intervention.

Methods: This pilot study utilized Ecological Momentary Assessment (EMA) methodology delivered on a mobile device to examine the relapse process and evaluate the utility of AR in former smokers attempting to remain abstinent postpartum. AR (or Control Training) was administered to abstinent smokers ($N = 17$) for up to 2 weeks both before and after delivery.

Results: All 17 participants completed the study. There was evidence that AR reduced attentional bias in the AR group (vs. Controls). There was no evidence that AR reduced craving. An exploratory analysis revealed that there was no evidence that AR reduced smoking during the study period.

Discussion: AR using EMA methodology *via* a mobile device is feasible in perinatal smokers. Further research using larger samples is required to evaluate the utility of mobile AR in reducing craving and smoking.

KEYWORDS

attentional retraining, ecological momentary assessment, relapse prevention, perinatal, craving, smoking abstinence

1. Introduction

Pregnancy and the postpartum period present unique opportunities and challenges for the 17 million reproductive age female smokers in the US (1). Smoking in the mother is associated with increased risks for cancer, heart disease, and chronic pulmonary disease, as well as adverse pregnancy outcomes (2–5). The health effects of second-hand smoke on newborns, which include increased risk for respiratory and ear infections, sudden infant death syndrome, behavioral dysfunction and cognitive impairment, are also significant (6). Close to half of women who were smokers prior to conception are able to quit smoking in pregnancy (7), but nearly 50% relapse within 2 weeks (8) and 80% relapse within a year after delivery (9, 10).

Other than contingency management (11–13), effective treatments for smoking in postpartum women are limited, as noted by the 2019 Cochrane review covering 77 studies, 19 of which specifically addressed perinatal populations (14). Psychotherapeutic interventions are only modestly effective in this population (14–18). For example, while a motivational and problem solving based intervention for perinatal patients temporarily increased the maintenance of postpartum smoking abstinence, relapse rates increased over time diminishing the effect of the treatment (18). In addition, the efficacy and safety of pharmacologic treatments for smoking are not yet established in pregnant and postpartum women (15, 19, 20). Thus, new, efficacious behavioral interventions are needed for perinatal women.

To develop effective interventions to prevent postpartum smoking relapse, it is imperative to understand the factors and psychological processes that influence return to smoking following delivery. Negative affect, stress, and urges/cravings have been implicated in relapse (21, 22). The factors influencing relapse in perinatal populations, as reported by mothers, include stress or the presence of another smoker which may induce craving (8). Other studies have reported that second-hand smoke exposure (23) and depression (24) have a strong influence on postpartum smoking relapse. Ecological momentary assessments (EMA) provide repeated sampling of real-world events, as they are influenced by environmental and situational cues. The use of EMA facilitates the study of situational factors that may serve as predictors of smoking in real-time. EMA data can also capture how individuals are differentially affected by factors such as affect and craving (25).

Another factor that influences smoking is "attentional bias" (AB) to smoking cues. AB is defined as the tendency to automatically attend to and maintain attention on smoking cues, and may be causally related to craving and use/relapse (26–28). Empirical research has shown that lower levels of AB are associated with higher success rates of short-term abstinence in smokers attempting to quit (29). Thus, a reduction in AB may reduce the likelihood of attending to smoking-related cues that could provoke craving. AB can be reduced through attentional retraining (AR), in which modified cognitive tasks are used to train participants' attention away from salient stimuli. For example, in the current context, AR seeks to train perinatal former smokers to automatically attend away from smoking cues and toward neutral cues, i.e., reduce AB. The effects of AR may transfer to real world stimuli, meaning that individuals undergoing AR would be less likely to attend to smoking cues in the environment, and therefore experience less cue-provoked craving. Both laboratory and field studies have demonstrated that AR can reduce AB toward smoking-related stimuli (28, 30).

AR has not been evaluated in perinatal smokers or perinatal former smokers. In a perinatal population, it may be useful to administer AR on a mobile device, given the promise of these methods in this population (31). In this randomized controlled pilot study, we tested the effect of AR of smoking cues administered on mobile devices, both prepartum and postpartum, in perinatal former smokers attempting to remain abstinent. We examined whether AR delivered on a smartphone can reduce AB to smoking-related stimuli and reduce craving for cigarettes. We also examined the effect of AR on smoking during the study period, and explored whether study phase (prepartum vs. postpartum) moderated the effect of AR on study outcomes.

2. Methods

2.1. Participants

Participants ($N = 17$) were recruited from the obstetrical clinics at Yale New Haven Hospital. Participants self-identified their race/ethnicity as: 9 Black, non-Hispanic; 4 Black, Hispanic; 2 White, Hispanic; 1 White, non-Hispanic, 1 other (West Indian). Inclusion criteria were: 1) a history of smoking 5+ cigarettes/day and having achieved abstinence by 32 weeks' gestation; 2) aged 18 to 40 years; 3) able to speak and write English; 4) Edinburgh Postnatal Depression Scale (EPDS) score < 10. Exclusion criteria included: 1) current substance use (e.g., alcohol, marijuana); 2) current major depressive disorder, minor depression, or history of any of such in the last 6 months; 3) presence of an Axis I psychotic disorder; 4) plan to relocate out of the area; 5) imminent incarceration; 6) planned inpatient hospitalization during study period. All participants had to meet these eligibility requirements before they could be enrolled and randomized to either condition. Data collection took place between May 2014 and February 2015.

2.2. Study design

This was a double-blind randomized controlled pilot trial. Enrolled participants were assigned to one of the two study conditions through "urn" randomization to ensure relatively equal allocation between treatment group (AR) and control with respect to age and severity of nicotine dependence. Participants and investigators were blinded as to study condition.

2.3. Procedure

Figure 1 provides an overview of procedures. Pregnant patients awaiting a routine prenatal visit were invited to complete a screening survey to determine provisional eligibility after providing screening consent. Forty-one women were screened, 20 women were eligible, and 17 were enrolled in the study (Supplementary Figure S1). After screening, provisionally eligible women that were < 32 weeks' gestation were followed until they reached 32 weeks' gestation. Those who were still eligible for randomization at 32 weeks completed an intake interview (Visit 1) that included a review of study procedures and consent, computer administered intake assessments (Supplementary Table S1), collection of urine for toxicology and cotinine analysis, and breath sample for carbon monoxide analysis.

Following randomization participants were instructed to carry a smartphone (LG Fathom) as they went about their daily lives for 2 weeks (Phase 1). Participants were locked out of all functions other than the program and told they were to complete four random assessments (RAs) per day. To increase adherence, participants could use the "delay" feature if they needed to delay the task by 5 min (up to four times per day). A "suspend" option could be used if a participant needed to prevent the phone from presenting assessments for a specific time period. Participants could also "make-up" a training/assessment if they missed an RA or experienced technical difficulties.

After 2 weeks, participants were contacted *via* phone (Visit 2) and instructed that Phase 1 was completed and daily RAs were suspended.

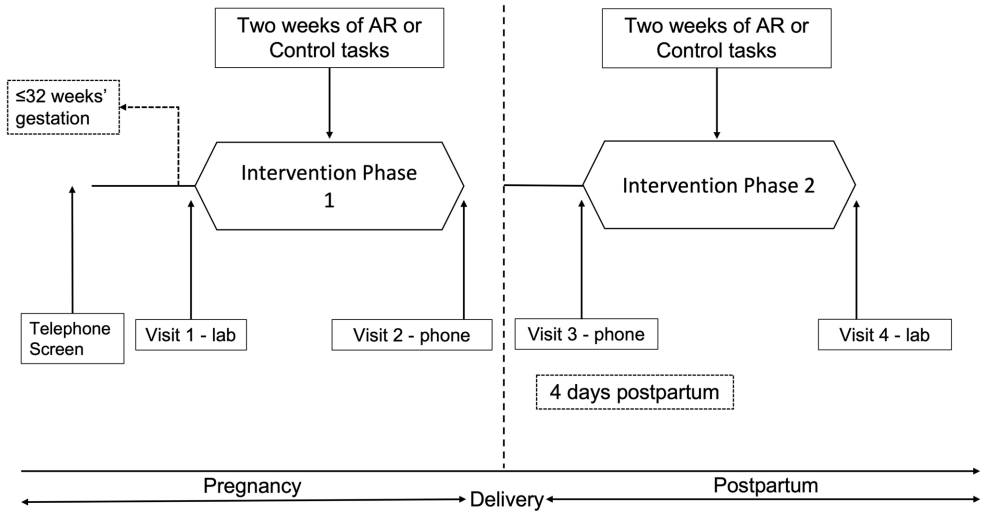

FIGURE 1
Procedures overview and timeline.

Approximately 4 days following delivery, participants began Phase 2, and were instructed *via* phone (Visit 3) to repeat the procedures from Phase 1. After 2 weeks they returned to the research clinic and completed Visit 4 assessments (Supplementary Table S1).

2.4. Measures

2.4.1. Assessments

Measures administered at visits are listed in Supplementary Table S1 along with their psychometric properties (see Supplementary material S1). The Mini-International Neuropsychiatric Inventory 5.0.0 Clinician-Rated (MINI-CR) assessed the presence of a mood, psychotic, or substance use disorder (32). The Fagerstrom Test for Nicotine Dependence (FTND) assessed severity of nicotine dependence (33). The Parenting Stress Index (PSI)-Short Form (34) assessed parental stress. The Minnesota Nicotine Withdrawal Scale (M-NWS) (35) assessed symptoms of nicotine withdrawal. The Brief Questionnaire on Smoking Urges (BQSU) (36) assessed urges/craving for cigarettes "right now." The Timeline Follow-Back (TLFB) assessed reported cigarette smoking for the prior week (37). All of these scales have been validated to suit research conducted in the U.S. and have been used in prior research with this population.

Breath carbon monoxide (CO) levels were used to confirm reports of abstinence. Participants' expired breath CO level was measured with a Vitalograph Breath CO device (CO level of <4 ppm was used to indicate abstinence from smoking). The NicAlert® assay was used for the urine cotinine analysis which gives an output on a "0" to "6" ordinal scale; <3 was used to indicate abstinence from smoking.

2.4.2. EMA procedures

EMA items, administered at RAs and make-up assessments, included the following: (1) overall mood and seven affect items (happy, calm, bored, sad, tense, irritable, tired) on a 7-point scale (1 = strongly disagree, 7 = strongly agree); (2) four items adapted from the Parenting Stress Index ("I feel I cannot handle things"; "I feel trapped by parenting"; "I feel overwhelmed by trying to meet my baby's needs"; "Since the last assessment, my baby has been difficult to console"); (3) two items assessing recent smoking; (4) three items assessing general context; (5) two items assessing smoking context ("Right now, is anyone smoking around you? If so, who?"; "If you smoked a cigarette, was anyone else smoking around you at the time? If so, who?"); and (6) an item assessing craving for cigarettes a 7-point scale (as above) following exposure to a picture containing both smoking and non-smoking stimuli presented for 1 s, as described in Kerst & Waters. (30).

2.5. Intervention

At each assessment (RA or make-up), participants completed either a training task (AR or Control) (75% of RAs/make-ups), or a "standard" visual probe (VP) task (assessment of AB) (25% of RAs/make-ups).

2.5.1. Standard VP task

In a standard VP task, a pair of pictures (e.g., one smoking-related and one neutral) is briefly presented (for 500 ms) simultaneously side by side on a computer screen. When the pictures disappear, a probe stimulus (e.g., a small dot) is presented in the location that had been occupied by one of the pictures (either on the left or the right), and participants are required to press a key as quickly as possible in response to the probe. AB for smoking-related cues is revealed by a faster response to a probe that replaces a smoking-related stimulus (vs. a neutral stimulus), since attention will have been allocated to the location where the smoking picture had been. Note that the standard VP task is an assessment of AB, and the assessment is not intended to change AB. The standard VP task was scored using typical procedures (see Supplementary material S2, S3).

2.5.2. AR and control training conditions

On 3 of the 4 RAs scheduled each day, participants were scheduled to complete a training task (AR or Control), 160 trials each. On 1 of the 4 RA scheduled each day, participants were scheduled to complete the standard VP task (for assessment of AB), 80 trials each. During the standard VP task, the dot is equally likely to replace the neutral or smoking picture. Fifteen picture sets consisting of 20 picture pairs (one smoking-related and one neutral) each were used for the tasks. Images were displayed for 500 ms. One picture set was administered on each study day (days 0–14 in pregnancy and days 0–14 postpartum). For the AR condition the VP task was modified so the dot always replaced the neutral picture. In the Control condition the dot was equally likely to replace the smoking stimuli and the neutral stimuli ensuring no correlation between the picture type and dot location, thus avoiding training of attention. This type of control condition also ensures equivalency between the AR and control conditions in terms of task duration, motor practice and stimuli presented (38).

2.6. Data analysis

For both AB and craving, a linear mixed model (LMM) was used. Models included Group (AR vs. Control), Phase (Pre- vs. Postpartum), Day (within Phase) and, where appropriate, the Group x Day interaction. The primary analyses tested the main effect of Group and the Group x Day interaction. For Smoking, a binary outcome, a generalized linear mixed model was used (GLMM). Sample size considerations are reported in the Supplementary material S4. Data analysis was conducted with SAS version 9.4.

3. Results

3.1. Lab descriptive statistics

Seventeen subjects enrolled in the study, and all attended the final laboratory visit and reported completing at least some training (AR vs. Control). Fourteen subjects contributed EMA data. One subject returned the phone with the memory card removed (resulting in loss of EMA data), and EMA data from two other subjects could not be retrieved due to technical problems (see Supplementary material S5). Participant characteristics are summarized in Table 1. The mean age of participants was 27.88 years, and a high percentage self-identified as Black (76.5%). There were no significant Group (AR vs. Control) differences on age or race (Table 1). There were also no significant Group differences on the PSI, EPDS, MNWS, QSU-Brief, or CO (Supplementary Table S2).

3.2. EMA descriptive statistics

The 14 participants who provided EMA data completed 575 trainings/assessments in total, with 290 from participants in the AR group and 285 from participants in the Control group. In the Control group, 164 of the trainings/assessments were RAs and 121 were make-up. In the AR group, 93 of the trainings/assessments were RAs and 197 were make-up. In total, there were 257 RAs and 318 make-up trainings/assessments (see Supplementary material S6). On days on which participants completed at least one training or assessment, participants completed (either by an RA or make-up) a median of 73.86% of the expected number of trainings/assessments. Completion rate was not significantly associated with age ($p = 0.40$), number of children ($p = 0.70$), prior smoking rate ($p = 0.77$), FTND ($p = 0.38$), or EPDS score at baseline ($p = 0.62$).

3.3. Number of trainings

Across both prepartum and postpartum EMA phases, participants in the AR condition ($n = 7$) completed a mean of 28.29 ($SD = 13.47$) AR trainings, and Control participants ($n = 7$) completed a mean of 23.71 ($SD = 12.63$) Control trainings. The two groups did not differ in the number of trainings completed, t (12) =0.65, $p = 0.52$. Across phases, participants in the AR condition ($n = 7$) completed a mean of 8.14 ($SD = 4.26$) VP assessments, and Control participants ($n = 7$) completed a mean of 8.00 ($SD = 4.58$) VP assessments. The two groups did not differ in the number of VP assessments completed, t (12) =0.06, $p = 0.95$. Summary statistics on dependent variables by Group and Phase are presented in Supplementary Table S3.

3.4. AR effects

3.4.1. Effect of AR on AB

As shown in Table 2, AR significantly reduced AB. AB was about 49 ms lower in the AR group (*vs* Controls), corresponding to an effect size $r = 0.66$ when using the formula used by Kashdan et al. (39). Phase was not significant in the model ($p = 0.69$), meaning there was no evidence that AB changed across phases. The effect of AR on AB remained significant when controlling for recent smoking ($t = -2.36$, $p = 0.04$). To examine whether AB declined more over time in the AR group (*vs* Control) within Phases, a Group x Day interaction term was tested. Day within Phase, and the Group x Day interaction term, were included in a model that also included Group and Phase. When coefficients for Day were treated as fixed, the Group x Day interaction was significant ($PE = -13.68$, $SE = 5.36$, $t = -2.60$, $p = 0.01$), indicating that AB declined more over time in the AR group than Controls. When coefficients for Day were treated as random (i.e., allowed to vary over participants), the Group x Day interaction was not significant ($PE = -22.63$, $SE = 13.00$, $t = -1.74$, $p = 0.11$). Figure 2 presents summary data for AB as function of Group (AR vs. Controls) and days within phase (days 1–7, 8–14).

3.4.2. Effect of AR on craving

There was a non-significant main effect of AR on the EMA measure of craving (Table 2). Across all assessments, craving ratings were actually (non-significantly) higher in the AR group (vs. Control) (Supplementary material S3). Phase was not significant in the model ($p = 0.26$), meaning there was no evidence that craving changed across phases. We examined whether Craving declined more over time in the AR group (*vs* Control) within Phases by testing a Group x Day interaction term. Day within Phase, and the Group x Day interaction term, were included in a model that also included Group and Phase. The Group x Day interaction was not

TABLE 1 Baseline measures.

Assessment ↓	All	AR	Control			
	N = 17	*n* = 9	*n* = 8			
	Mean (SD) or n (%)	*Mean (SD) or n (%)*	*Mean (SD) or n (%)*	*t/Chi Square*	*df*	*p*
Age	27.88 (*SD* = 4.92)	26.33 (*SD* = 4.18)	29.63 (*SD* = 5.37)	−1.42	15	0.18
Race/Ethnicity				4.78	2	0.31
Black	13 (76.5%)	8 (88.9%)	5 (62.5%)			
Puerto Rican	1 (5.9%)	0 (0.0%)	1 (12.5%)			
White	3 (17.7%)	1 (11.1%)	2 (25%)			
Hispanic Heritage				3.29	2	0.19
Puerto Rican and Dominican	1 (5.9%)	0 (0.0%)	1 (12.5%)			
Puerto Rican	4 (23.5%)	1 (11.1%)	3 (37.5%)			
None	12 (70.6%)	8 (88.9%)	4 (50.0%)			
Education (years)	11.71 (*SD* = 1.53)	11.11 (*SD* = 1.69)	12.38 (*SD* = 1.06)	−1.82	15	0.09
Employment				4.39	2	0.11
Full-Time	7 (41.2%)	4 (44.4%)	3 (37.5%)			
Part-Time	3 (17.6%)	0 (0.0%)	3 (37.5%)			
Not Working	7 (41.2%)	5 (55.6%)	2 (25%)			
Average Cigarettes Smoked/Day	11.00 (*SD* = 10.86)	9.78 (*SD* = 9.86)	12.38 (*SD* = 12.42)	−0.48	15	0.64
Age Smoking Initiation	15.65 (*SD* = 3.35)	16.44 (*SD* = 3.61)	14.75 (*SD* = 3.01)	1.04	15	0.31
Most Cigarettes Smoked per Day	17.18 (*SD* = 16.44)	12.22 (*SD* = 11.29)	22.75 (*SD* = 20.12)	−1.35	15	0.20
FTND	3.06 (*SD* = 2.84)	2.67 (*SD* = 3.16)	3.50 (*SD* = 2.56)	−0.59	15	0.56
Number of Pregnancies	4.00 (*SD* = 2.37)	4.33 (*SD* = 2.60)	3.63 (*SD* = 2.20)	0.60	15	0.98
Number of Births	1.88 (*SD* = 1.17)	1.89 (*SD* = 0.60)	1.88 (*SD* = 1.64)	0.02	15	0.98
Number of Children	1.47 (*SD* = 0.94)	1.67 (*SD* = 0.50)	1.25 (*SD* = 1.28)	0.90	15	0.38

Chi square statistics reflect pearson chi square statistics. Similar results are obtained using Fisher's Exact Test.

TABLE 2 LMM analyses.

			Numeric DV					Binary DV				
IV↓	DVs ↓	*n*	*df*	*PE*	*SE*	*F*	*P*	*Df*	*PE*	*SE*	*F*	*p*
Group (AR vs. Control)	Attentional Bias	271	1, 7.16	−48.54	20.52	5.59	0.04	.	.	.	.	.
Group (AR vs. Control)	Craving	575	1, 10.70	0.46	0.92	0.25	0.63	.	.	.	.	.
Group (AR vs. Control)	Smoking	565	.	.	.	.	.	1, 9.74	0.26	0.96	0.08	0.79

Data are results from LMMs (continuous outcomes) and GLMM (binary outcome). 7 AR subjects and 7 Control subjects contributed data to analyses. n = number of assessments. All models include Phase (parameter estimates for Phase not shown). df = Satterthwaite degrees of freedom, PE, parameter estimate, SE, standard error. Group coded as 0 = Control, 1 = AR.

significant when coefficients for Day were treated as fixed (*PE* = 0.05, *SE* = 0.05, *t* = 1.00, *p* = 0.32), or random (*PE* = 0.11, *SE* = 0.11, *t* = 1.03, *p* = 0.34).

3.4.3. Effect of AR on smoking

There was no evidence for a significant main effect of AR on smoking (Table 2). Phase was not significant in the model (*p* = 0.65), meaning there was no evidence that levels of smoking changed across phases. Regarding assessment of relapse, defined as any self-reported smoking during the study period, 3 participants (21.4% of 14 participants) reported no smoking during the entire study period, with abstinence confirmed with biochemical assessments, and 11 participants (78.6% of 14 participants) reported relapse. Two abstinent participants were in the AR group (28.6% of AR group) and 1 abstinent participant was in the Control group (14.3% of Control group).

3.5. Exploratory analyses

Exploratory analyses revealed that there was no evidence that the effect of Group was different in the two phases (see Supplementary material S7). In a supplementary analysis (see Supplementary material S8), we examined whether craving ratings declined over time. To be consistent with a previous study (28), analyses were conducted on the first two weeks of data collection (in this case, prepartum data). The effect of Day was significant for

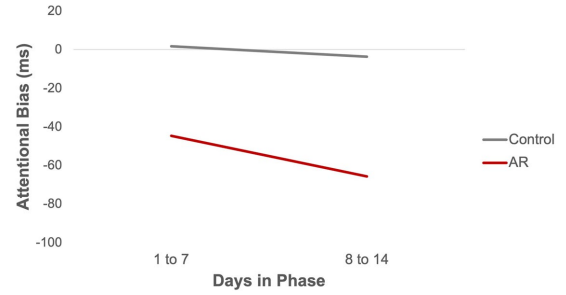

FIGURE 2
Attentional bias by group.

Craving, F (1, 8.06) = 5.92, p = 0.04, indicating that Craving declined over time. This model included Group and Day (Day was a level 1 numeric variable and coefficients for Day were treated as random). Additionally, when the Group by Day interaction was added to the model it was not significant, F (1, 7.62) = 0.21, p = 0.66. This means that the declines in Craving over time were not significantly different between the AR and Control groups.

4. Discussion

The main results of this pilot study of AR were as follows. First, there was evidence that AR reduced AB to smoking cues in perinatal women. Second, women in the AR group did not report significantly less craving than women in the Control group. Third, women in the AR group did not report a significantly lower rate of smoking than women in the Control group. Additional separate analyses by phase demonstrated that there was no evidence the effect of AR on study outcomes was different in the two phases (pre vs. postpartum).

Compared to Control training, there was evidence that AR reduced AB, as assessed by the VP task. AB was reduced about 50 ms in the AR compared to the Control group. This finding is consistent with other data suggesting that AR administered by the modified VP task can reduce AB as assessed by VP task [e.g., Robinson et al. (28)]. This suggests that AR can reduce AB in perinatal smokers when administered on a smartphone.

Although a significant effect of AR was observed, the following caveats should be noted. First, as noted earlier, the effect of Group was significant when all participants who provided EMA data (n = 14) were included in analyses ("intent-to-treat" analysis). However, the effect of Group was not significant in analyses restricted to individuals who were abstinent at baseline and who provided EMA data (n = 13). Therefore, more research is required to examine if the effect of AR in abstinent perinatal smokers is robust. Second, it was interesting that participants in the Control group did not exhibit significant AB. This is in contrast to data from participants who received Control training in previous studies (28, 30). However, one should bear in mind that the sample size in the Control group in the current study (n = 7) was smaller than sample sizes in other studies.

Compared to Control training, there was no evidence that AR reduced craving. This finding applied to craving assessed in the lab and field. This finding differed from those reported in a previous study (30). However, a null effect of AR on craving has also been reported in past research and thought to be due to the pictures not eliciting craving, thus compromising the ability of AR to reduce cued craving (28). It is also possible that in a natural, real-world environment, participants can become distracted and miss seeing the pictures, as the cues were presented for only 1 second.

Reported craving trended downward in pregnancy during Phase 1. Since there was no significant difference between the effect of Day in the two groups (AR and Control), this suggests a similar decline in craving in the two groups. Other researchers have reported that both AR and Control training can yield positive outcomes (40, 41). For example, Pettit et al. in an RCT of AR targeting pediatric anxiety found beneficial changes in both the AR and Control group (41). They speculated that both AR and attentional control training can reduce anxiety through repeated practice focusing, sustaining, and shifting attention which improves regulatory abilities improved in both groups. This suggests a different mechanism related to training flexible deployment of attention rather than a mechanism of change involving automatic attention allocation. These findings emphasize the need for further research regarding whether multiple cognitive mechanisms are affected during AR. However, given the absence of a no-treatment control group, these results should be treated with caution. Given that these finding were only seen in pregnancy, it is possible that declines in craving could have been independent of the AR or Control tasks, and due to other pregnancy related factors. For example, progesterone levels are at their highest in the late third trimester which is when participants engaged in the Phase 1. Progesterone is shown to decrease craving for nicotine in clinical studies (42, 43).

There was no significant effect of AR on smoking assessed on the smartphone, or on a biological measure of smoking assessed at the lab. Wiers and colleagues have argued that the effects of AR on drinking outcomes are more robust in clinical populations, who are generally strongly motivated to maintain abstinence, than in student samples or samples recruited online (44). Although our sample were recruited in a clinical context, and had made an attempt to abstain from smoking during pregnancy, there is still uncertainty regarding the level of motivation to remain abstinent after delivery. As noted, the relapse rate was high. Many mothers quit during the pregnancy for the health of the baby, but are not motivated specifically for their own health. Therefore, their level of motivation to remain quit after giving birth may greatly diminish, depending on where this motivation originated. It is possible that AR may only be effective in a selected sample of perinatal former smokers who are highly motivated to quit for good, rather than just "pausing" smoking during the prepartum period.

This study had a number of limitations. First, the sample size was small, which reduced power of analyses. The analytic sample size was further reduced by loss of data due to technical limitations. Therefore the findings, particularly the null effects of AR on craving and smoking, should be interpreted with caution pending further research with larger sample sizes. Nonetheless the data and findings may be useful for researchers for estimation of effect sizes and/or for use in meta-analyses. Second, due to participants' extensive use of make-up assessments (rather than RAs) data from the study is likely less "random" than data from a study solely using random assessments. Use of make-up assessments reduces the generalizability of study findings and can potentially lead to bias in parameter estimates. Third, there were limitations regarding the assessment of AB. There was no baseline assessment of AB, meaning that it was not possible to determine whether the two groups differed at baseline. The study did not assess whether the effect of AR on attention generalized to different stimuli type (e.g., words) or to performance

on a different attention bias task. Fourth, the use of a single item for craving of unknown reliability could be considered a limitation. Finally, while the main focus of the study was to examine AR in abstinent perinatal former smokers, there was evidence that one participant had smoked prior to randomization. Results should be interpreted in light of the fact that both abstinent and the non-abstinent individual were included in the intent-to-treat sample.

The study also had strengths. First, and most importantly, this was the first study to develop and administer an AR intervention for perinatal former smokers, a group at high risk of relapse. Second, another strength was the recruitment of an underserved minority population who are at risk of relapse and lifelong smoking.

Results from this study provide evidence that perinatal women can tolerate several days of training and that AR reduces AB in the field. Future research can build off the results of this study. It is possible that the effect of AR on outcomes is diluted by the presence of assessments administered in the field. Assessments were similar to Control trainings, and so future studies might manipulate the proportion of assessments to AR trainings in order to examine whether changes in proportion influence the effect of AR. As noted in the introduction, AR can be easily modified and has been modified for various health conditions and behaviors, such as healthier eating (i.e., train away from unhealthy food) and anxiety (i.e., train away from a perceived threat) (45, 46). Future research could examine the efficacy of training participants toward healthier behaviors or away from stress-related stimuli. Third, future research should evaluate factors that impact participant smoking behavior such as plans to breastfeed, and participants' intention to remain quit or their motivation to quit. Lastly, examining the combined effect of AR with commonly used cessation treatments (e.g., CBT) is necessary to determine how much of an incremental effect AR can truly have in the real world.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by Yale University Institutional Review Board. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

AF and AW contributed to the study's conception, design, and data acquisition. AF, AW, and RG contributed to the analysis and interpretation of the data and the first draft of the manuscript. AW and RG performed the statistical analysis. CM wrote sections of the manuscript. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

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Substance use during pregnancy and risk of postpartum depression: a systematic review and meta-analysis

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Introduction: Postpartum depression (PPD) is a prevalent mental health condition affecting women globally within the first year following childbirth. Substance use during pregnancy has been associated with an increased risk of developing PPD, but the evidence remains inconclusive. This meta-analysis aims to comprehensively assess the effects of different substances on PPD risk, exploring potential modifiers and confounding factors.

Objectives: To examine the proportion of PPD among substance users during pregnancy, compared to non-users, and investigate the specific risk associated with different substances (tobacco, alcohol, and non-specified substance use/multiple substance use).

Methods: A systematic literature search was conducted from inception to November 2022 using the Web of Science database (Clarivate Analytics), incorporating Web of Science Core Collection, the BIOSIS Citation Index, the KCI-Korean Journal Database, MEDLINE®, the Russian Science Citation Index, the SciELO Citation Index, and the Cochrane Central Register of Reviews, and Ovid/PsycINFO databases. Inclusion criteria comprised original studies with pregnant women, using validated depression scales and substance use reporting.

Results: Among the 26 included studies, encompassing 514,441 women, the pooled prevalence of PPD among substance users during pregnancy was 29% (95% CI 25–33). Meta-analyzes revealed an overall odds ratio (OR) of 3.67 (95% CI 2.31–5.85, $p<0.01$) indicating a significantly higher risk of PPD among substance users compared to non-users. Subgroup analyzes demonstrated a higher risk for women with non-specified or multiple substance use (OR 4.67, 95% CI 2.59–8.41; $p<0.01$) and tobacco use (OR 4.01, 95% CI 2.23–7.20; $p<0.01$). Alcohol use showed a trend toward higher risk that did not reach statistical significance (OR 1.88, 95% CI 1.00–3.55; $p=0.051$).

Conclusion: This meta-analysis provides evidence of an increased risk of PPD among pregnant substance users, particularly those using multiple substances or tobacco. However, caution is needed in interpreting the association with alcohol use due to its non-significant result.

Systematic review registration: This study protocol was registered at PROSPERO (registration number: CCRD42022375500).

KEYWORDS

perinatal, postpartum, postpartum depression, substance use disorder, alcohol use disorder, tobacco

1. Introduction

1.1. Background

Postpartum depression (PPD) is a mental health condition affecting many women worldwide within the first year following childbirth (from 10% up to 17%) (1–3). PPD is characterized by a range of depressive symptoms that can significantly impact the mother's well-being and potentially hinder the optimal development of the infant (4–7).

Multiple risk factors have been identified concerning the development of PPD (6, 8, 9) such as low socio-economic status, substance use, poor physical health, history of depressive disorders, multiple births or preterm births. Of particular significance is the association between PPD and substance use during pregnancy (8). Women's risk of developing a substance use disorder is highest between 18 and 29 and remains elevated throughout their reproductive years (10, 11). According to a national survey conducted in the United States in 2013, it was estimated that up to 5% of pregnant women engage in substance use (12). However, it may be underdiagnosed due to fear of stigma and the social and legal consequences of using illicit drugs during pregnancy (13).

Substance use during pregnancy, including tobacco, alcohol, cannabis, and other substances, poses immediate risks to the health of both the mother and the developing fetus (8, 14–16) Substance use during pregnancy is strongly discouraged, and pregnant women are encouraged to seek abstinence. Additionally, pregnancy can serve as a window of opportunity in which women may be more receptive to changing behaviors to safeguard their developing child (17–19). Nonetheless, despite many women successfully achieving and maintaining abstinence during pregnancy, there is a significant tendency to relapse within the first year after childbirth, a particularly crucial period for developing a strong mother-baby bond, which is essential for healthy infant development (10, 20). Substance use has also been associated with several negative outcomes in the offspring, such as mental health problems in childhood and adolescence (21, 22), increased psychosis risk (23) and metabolic health conditions (24).

For previous reasons, addressing substance use during pregnancy and providing comprehensive support for mothers with a previous history of substance use during the postpartum period is crucial to mitigate the potential negative effects of substance use on maternal well-being and infant development.

Although several studies have examined the association between substance use during pregnancy and the development of postpartum depression (PPD) (8, 25–27), no meta-analysis has provided a comprehensive evaluation of the combined effects of different substances on the risk of PPD.

We aim to examine the proportion of postpartum depression (PPD) among substance users during pregnancy, both overall and specifically for different substances. Secondly, we assess the extent to which women with substance use during pregnancy exhibit higher PPD rates compared to those without substance use, again considering overall rates and rates specific to different substances. Lastly, we explore the influence of confounding factors, such as sample characteristics, e.g., age, marital status, or primiparity, and methodological factors, including the study risk of bias in PPD rates.

2. Methods

This study protocol was registered at PROSPERO (registration number: CCRD42022375500). The study was conducted in accordance with "Meta-analyzes of Observational Studies in Epidemiology" (MOOSE) checklist (28) (Supplementary Table S1) and "Preferred Reporting Items for Systematic Reviews and Meta-Analyzes" (PRISMA) (29) (Supplementary Table S2), following "EQUATOR Reporting Guidelines" (30).

2.1. Search strategy and selection criteria

Two independent researchers (MP and BP) conducted a systematic search of the literature up until November 30, 2022. The searches were performed using the Web of Science database (Clarivate Analytics), incorporating the Web of Science Core Collection, the BIOSIS Citation Index, the KCI-Korean Journal Database, MEDLINE®, the Russian Science Citation Index, the SciELO Citation Index, and the Cochrane Central Register of Reviews, and Ovid/PsycINFO databases.

The following keywords were used: ("substance abus*" OR "substance us*" OR addict* OR "drug abuse" OR tobacco OR alcohol* OR cannabis OR THC OR cocaine OR amphetamine* OR stimulant* OR opioid* OR "illicit drugs" OR hallucinogens) AND (pregnan* OR antenatal OR prenatal OR perinatal OR postnatal) AND ("postpartum depression").

The inclusion criteria for the systematic review and meta-analysis were: (a) individual prospective or retrospective studies with original data reporting data of postpartum depression, defined as a depressive disorder with an onset within 6 weeks after delivery (31), (b) using a validated, structured scale to measure depressive symptoms, (c) in pregnant women of any age with any legal or illegal substance use

during pregnancy (32), and (d) written in English or Spanish. Exclusion criteria were: (a) reviews, clinical cases, study protocols or qualitative studies, conferential proceedings, letters, and commentaries, (b) reporting on patients on which the onset of current depression episode precedes the current pregnancy, and (c) written in languages other than English or Spanish.

Identified articles were first screened as abstracts, and after excluding those not meeting the inclusion criteria, the full texts of the remaining articles were assessed for eligibility. In case of disagreement a senior researcher (A.C.) made the final decision. The search was completed by manually searching through the references of previously published systematic reviews and meta-analyzes on the topic.

2.2. Data extraction

Three researchers (CA, RD, and IL-Z) independently extracted data from all the included studies. The databases were then cross-checked by an independent researcher (MP), and discrepancies were resolved by a senior researcher (AC).

A summary of selected variables included: first author and year of publication, country, recruiting period, study type (cross-sectionals, cohorts, case–control, clinical trial), sample size, age [mean ± standard deviation (SD)] for the total sample size and each subgroup, diagnostic tool for depression, type of drug used, duration of use, frequency of use, week of pregnancy in which the drug use started, week of pregnancy in which the drug use ceases, number of events (defined as PPD diagnoses in each study group), family history of substance use, parity, previous psychiatric diagnosis both recorded as a dichotomic variable and according to the DSM or ICD criteria (1, 32), and key findings. For numeric variables, mean and SD were collected.

When multiple data points were available in one study, the latest point recorded within the first year after delivery was coded. Studies were examined for samples overlap, determined by looking at the inclusion dates and type of population and country in which the study was carried out; in case of overlapping samples, the study with the largest sample was then selected.

2.3. Risk of bias (quality) assessment

Risk of bias was assessed using Newcastle-Ottawa scale (33) for cohort and cross-sectional studies (Supplementary Table S3).

2.4. Strategy for data synthesis and statistics

A systematic synthesis of the included studies was provided. Then, we performed two separate analyzes when allowed by the data presented in the original research. First, we performed meta-analyzes using, as primary effect size, the proportion [% and standard error (SE), when available] of PPD among substance users. Second, using those articles where a comparison control group (including women without substance use during pregnancy) was included, the odds ratio (OR) with a 95% confidence interval (CI) was calculated using the number of women with PPD and sample sizes for each sample (substance users and non-users). The comparison of effect sizes in each group was calculated using the effect size (ES) formula (34). An ES greater than 1 indicates the substance-user group has a higher risk of PPD than the non-user group.

In both analyzes all the available substances were pooled for a single analysis, and subgroup meta-analyzes were subsequently conducted for each substance where data allowed for it.

Meta-regressions were performed when a minimum of 7 papers were available to study the effects of (a) mean age of the sample, (b) Newcastle-Ottawa Scale (NOS) score, (c) % of married women of the sample, and (d) % of primiparous women. Subgroup analyzes were performed to study the influence of (a) depression rating scale, and (b) used substance on the outcomes. Heterogeneity among studies was assessed using Q statistics, with the proportion of the total variability in effect size estimates evaluated using the I^2 index, classifying the heterogeneity as low (I^2 = 25%), medium (I^2 = 50%), and high (I^2 = 75%) (35). Since heterogeneity was expected to be high, the random-effect model was used. Publication bias was assessed by visually inspecting funnel plots.

All analyzes were conducted within R software, version 1.4.1106 (36). The significance level was set at $p < 0.05$, two-sided.

3. Results

The literature search yielded 8,086 citations through electronic database, which were screened for eligibility; 88 articles were assessed in full text, and 62 were excluded. The final database for the systematic review and meta-analysis included 26 studies, as it can be seen in Figure 1 (29). A total sample of 45,914 women with substance use during pregnancy were included, with a mean age of 27.7 ± 3.1. 73.7% were married and 47.4% were primiparous. 61.5% of the studies used Edinburgh Postnatal Depression Scale (EDPS) (37) to rate depressive symptoms and the 38.5% of the studies used other criteria (mainly PHQ-2 scale and ICD-10 diagnostic criteria (32, 38)). 18 studies also included a control comparison group (encompassing a total of 468,527 women without substance use during pregnancy) thus allowing the calculation of an odds ratio for perinatal depression. Mean NOS score of the included studies was 6.6 ± 0.9 (Supplementary Table S4).

3.1. Prevalence of postpartum depression among women with substance use during pregnancy

Data were extracted for a total sample size of 36,008 women in 26 studies. 8 studies reported on women with alcohol use during pregnancy (39–45); 13 on women with tobacco use (39–49), and 10 (43.5%) on women with non-specified or multiple substance use (45, 50–56). The latest group included samples of pregnant women reporting multiple, non-specified use of legal drugs such as alcohol, tobacco and khat (50, 53, 54, 56) as well as non-specified illegal drugs, including amphetamines, cocaine and opioids (45, 51, 52, 55, 57, 58).

The pooled prevalence of postpartum depression (PPD) among women with substance use was 0.29 [95% confidence intervals (CI) 0.25–0.33; Figure 2]. When stratified by substance, women with alcohol use while pregnancy (n = 10,073) presented a prevalence of PPD of 0.23 (95% CI 0.11–0.34), while women using tobacco (n = 25,065) showed a prevalence of 0.27 (95% CI 0.20–0.34). Women

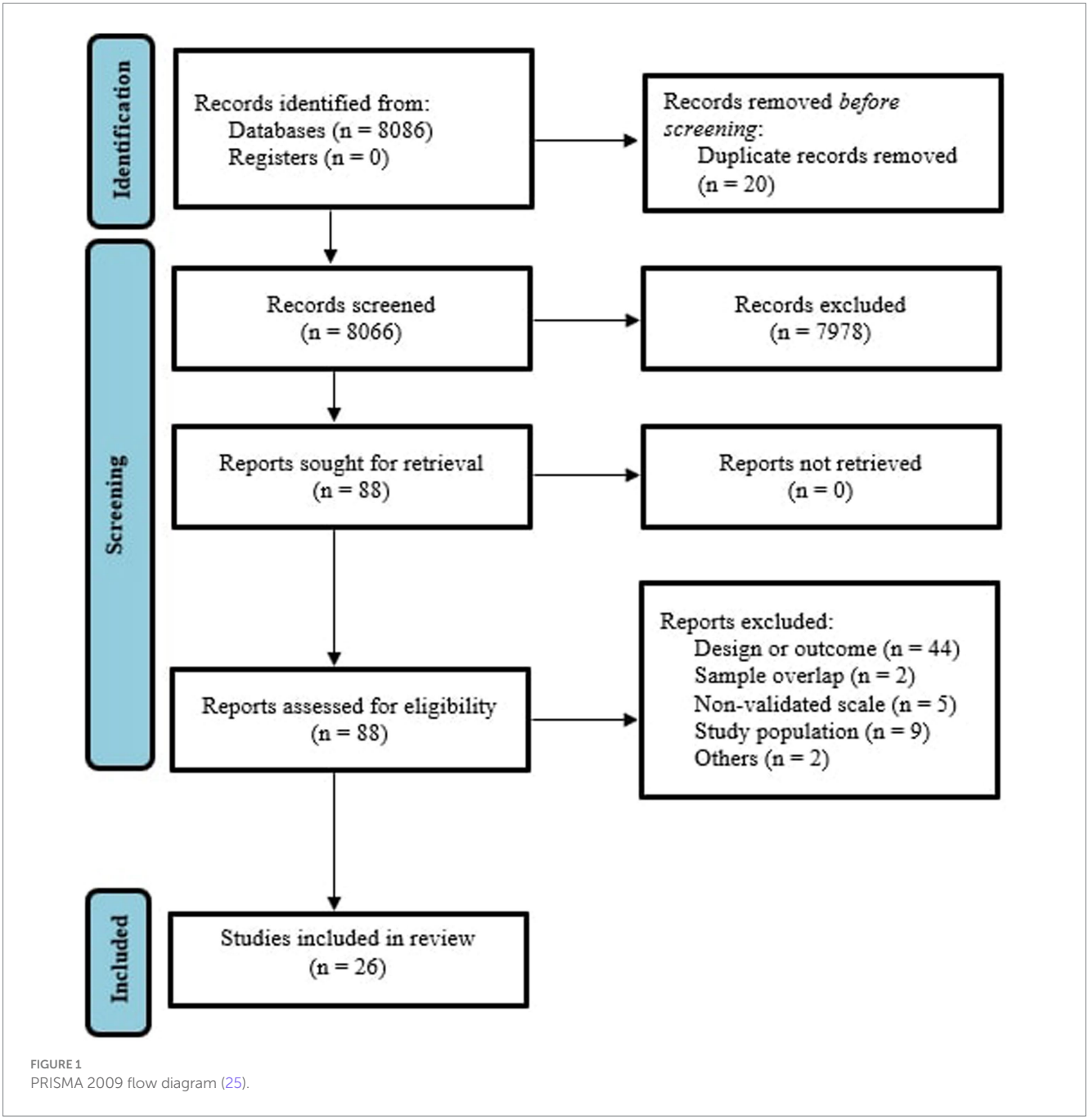

FIGURE 1
PRISMA 2009 flow diagram (25).

with non-specified substance use or using multiple substances (besides alcohol and/or tobacco) during pregnancy ($n = 870$) showed the highest rates of PPD, at 0.44 (95% CI 0.31–0.58). Heterogeneity was significant across all of the meta-analyzed substances ($p < 0.05$ for tobacco, alcohol and non-specified or multiple substance use), as well as on the pooled sample ($p < 0.05$; Table 1).

3.2. Odds ratio of postpartum depression among women with substance use during pregnancy compared to non-user pregnant women

Eighteen studies, including a sample of 485,305 women (16,778 with substance use during pregnancy and 468,527 non-users) were included. As shown in Figure 3, PPD prevalence was higher among women with substance use during pregnancy, with an OR of 3.67 (95% CI 2.31–5.85). When analyzed by substance Figure 4, women with non-specified or multiple substance use other than alcohol and/or tobacco ($k = 8$) presented the highest risk of PPD compared to non-users, with an OR of 4.67 (95% CI 2.59–8.41, $p < 0.01$), followed by women with tobacco use ($k = 11$), who showed an OR of 4.01 (95% CI 2.23–7.20, $p < 0.01$). Finally, women with alcohol use during pregnancy ($k = 7$) did not show a statistically significant difference with those without, although a trend toward significance was detected OR of PPD of 1.88 (95% CI 0.99–3.55, $p = 0.051$). Again, heterogeneity was significant ($p < 0.05$) across all of the meta-analyzed substances, as well as on the pooled sample (Table 2).

Meta-regressions showed no significant effect of age, NOS score, or % of primiparous women. Percentage of married women positively

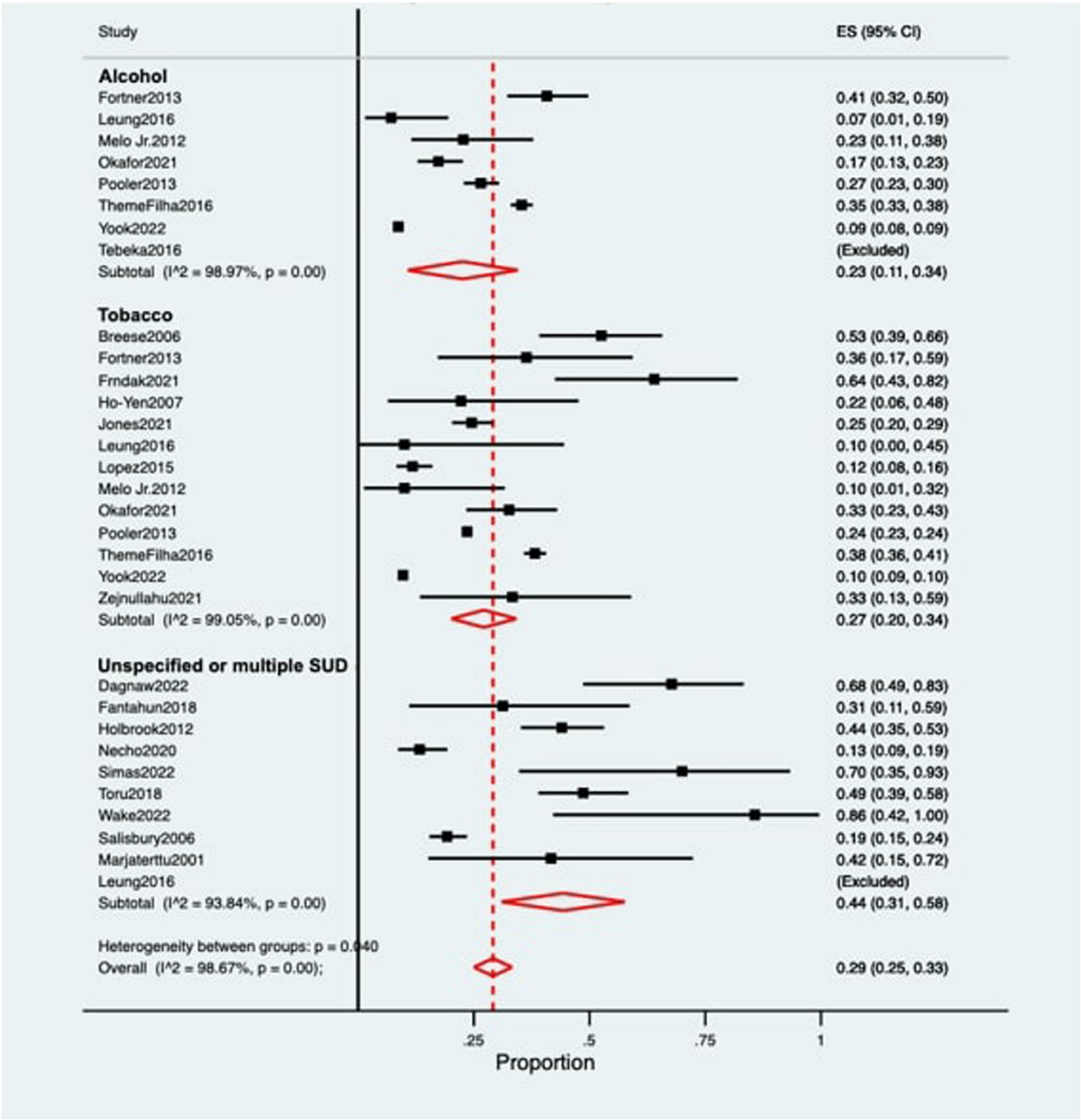

FIGURE 2
Forest plot for the prevalence of postpartum depression among women with substance use during pregnancy. ES, Effect Size; CI, Confidence Interval; SUD, Substance Use Disorder.

TABLE 1 Prevalence of postpartum depression among women with substance use during pregnancy.

Substance	No. studies	Sample size	Proportion	95% CI	*p* value	z Score	I^2 (%)
Alcohol	8	10,073	0.23	0.11–0.34	0.00*	3.72	98.97%
Tobacco	13	25,065	0.27	0.20–0.34	0.00*	7.60	99.05%
Non-specified or multiple SUD	10	870	0.44	0.31–0.58	0.00*	6.52	93.84%
Overall	23	36,008	0.29	0.25–0.33	0.00*	13.83	98.67%

CI, Confidence Interval; SUD, Substance Use Disorder. *Indicates statistical significance.

correlated with a greater OR of PPD (β 1.23; SE 0.58; *p* 0.04) for women with substance use (Table 3). Sensitivity analyzes showed no significant influence of the used depression rating scale on the outcome. Visual inspection of funnel plots did not suggest the presence of any publication bias for the analyzed groups (Supplementary Figures S1–S4).

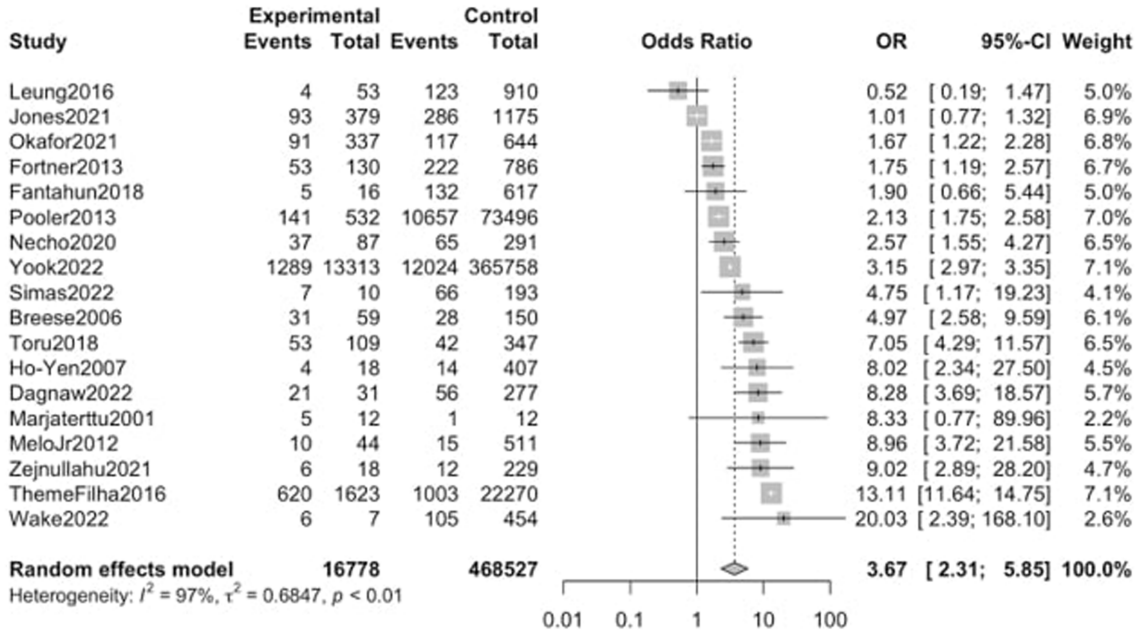

FIGURE 3
Forest plot for the odds ratio of postpartum depression among women with any substance abuse during pregnancy vs. women without. OR, Odds Ratio; CI, Confidence Interval.

4. Discussion

To the best of the authors´ knowledge, this is the first systematic review and meta-analysis examining both the prevalence of PPD in pregnant substance users and their odds ratio of PPD compared to non-users. The primary finding of this meta-analysis is the high prevalence of postpartum depression among substance-using pregnant women [OR 3.67, (95% CI 2.31–5.85)]. According to our analysis, a significant proportion (29%) of pregnant women who consume substances experience PPD, which is notably higher compared to other studies examining the prevalence of PPD in the general population, believed to be around 17% (3). Those reporting multiple concomitant use of legal and/or illegal substances showed the highest rate of PPD (34%), followed by women using tobacco (27%) and alcohol (23%).

Among all the potential confounding variables, only a significant effect of marital status was found, with a higher risk of PPD among samples with greater rates of married women. This finding may appear counterintuitive because the literature has reported a higher prevalence of PPD among those with less social support (59). However, several mediating factors, such as low perceived social support or marital dissatisfaction, which have been previously reported to be risk factors for postpartum depression (60, 61). This result could also potentially be attributed to the effect of domestic violence among married women, which would increase the risk of suffering PPD (62, 63). Unfortunately, we could not verify this hypothesis due to a lack of data in the articles included in our study.

4.1. Multiple and non-specified substance use

Women reporting the use of multiple legal and/or illegal substances during pregnancy presented the highest odds ratio for developing PPD [OR 4.67, (95% CI 2.59–8.41)]. These results align with previous findings reported in the literature, supporting the notion that substance use during pregnancy is a significant risk factor for PPD. As highlighted in the review by Pentecost (8), a substantial percentage of women with a history of substance use experience postpartum depressive symptoms, with estimates ranging between 20 and 60%. Furthermore, the study conducted by Onah et al. (64) showed that 18% of pregnant women who used alcohol and/or other drugs were currently experiencing a major depressive episode.

It is widely known that up to 1/3 of individuals with mental disorders may have comorbid substance use (65). Additionally, in women, the comorbidity between substance use and depression is higher than in men (65), partly due to the greater prevalence of affective disorders in women (66). Several theories have been proposed to explain this association. One theory suggests (53, 55) consumption of multiple substances alters brain neuroplasticity, which may contribute to the development of depressive disorders (67, 68). Another theory suggests that substance use and depression may be distinct manifestations of the same underlying neurobiological disorders (67, 68). Lastly, other studies show that may be a significant overlap between environmental factors impacting substance use and depression (67, 69) where stress may play a crucial role in this association, as it heightens the risk of both substance dependence and relapse (70) along with the occurrence of depressive episodes (55, 56, 67, 71).

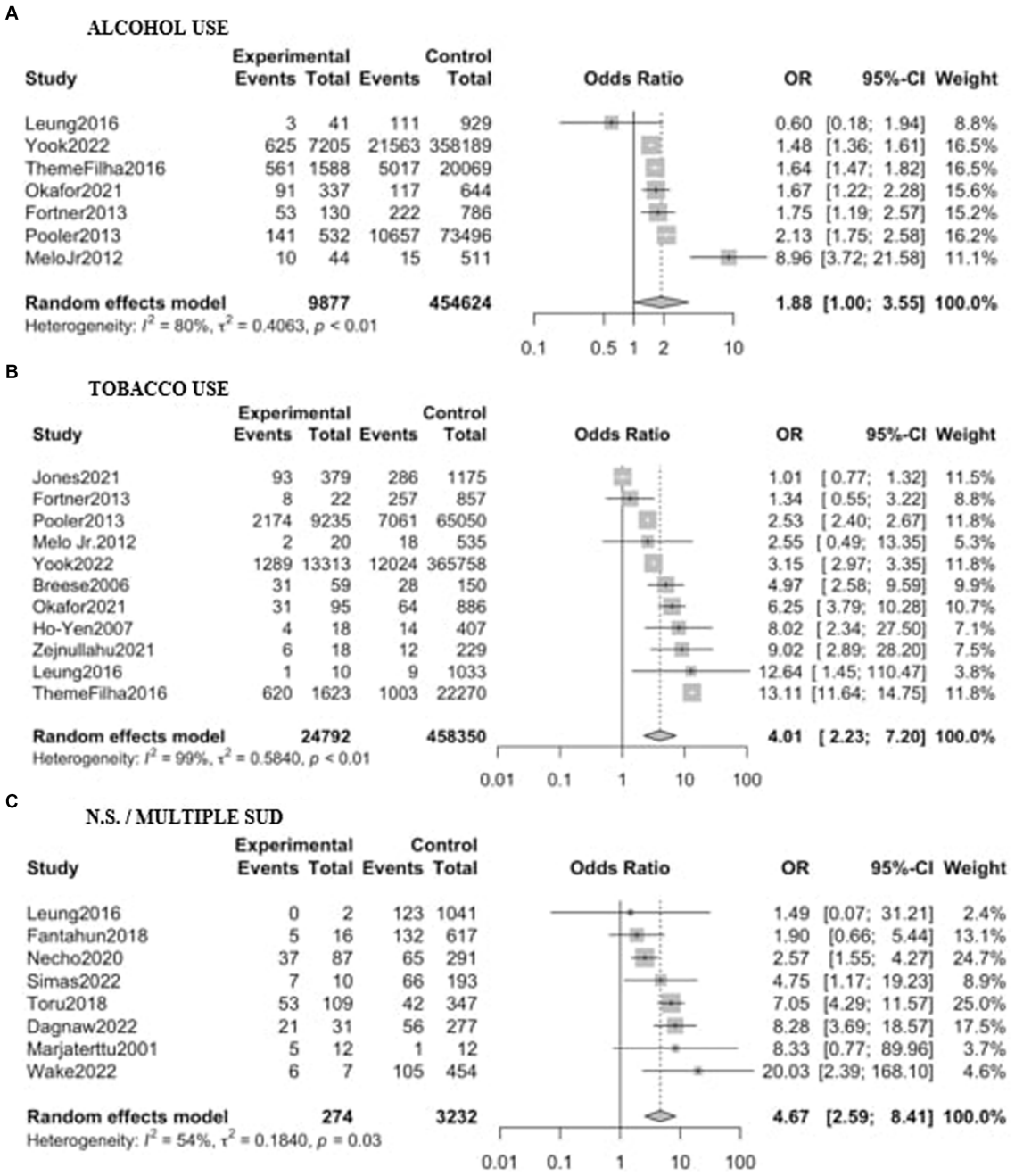

FIGURE 4
Forest plot for the odds ratio of postpartum depression among women with substance use during pregnancy vs. women without. Results are shown stratified by the substance used: **(A)** Alcohol; **(B)** Tobacco; **(C)** Non-specified/multiple substance use. OR, Odds Ratio; CI, Confidence Interval.

4.2. Tobacco use

Women reporting tobacco use during pregnancy showed an OR of 4.01 (95% CI 2.23–7.20, $p < 0.05$) of PPD compared with non-users, with a total prevalence of postpartum depression of around 27%. Tobacco smoking in pregnant women had previously been linked not only to greater rates of depression (72, 73) and anxiety (74) but also to increased suicidal ideation (75).

There are several explanations for this. Tobacco use during pregnancy is linked to disturbances in the intricate neuro-hormonal balance and neurochemical pathways involved in mood regulation, including a reduction in the levels of dopamine and GABA neurotransmitters (76) and an alteration of nicotinic acetylcholine receptors involved in the hypothalamic–pituitary–adrenal (HPA) axis (77). Nicotine administration has been found to enhance the HPA axis response to stress (78, 79), a known risk factor for depression (80). The HPA axis also undergoes great changes during pregnancy (thus impacting the stress response) (81), which could help explain pregnant women's particular vulnerability to tobacco exposure as suggested by our findings. Social factors could also contribute to the high rate of

TABLE 2 Odds ratio of postpartum depression among women with substance use during pregnancy compared to women without.

Substance	No. studies	OR	95% CI	*p* value	Test for heterogeneity		
					Q	I^2 (%)	*p*
Alcohol	7	1.88	0.99–3.55	0.051	29.4	79.6	<0.01*
Tobacco	11	4.01	2.23–7.20	<0.01*	707.0	98.6	<0.01*
Non-specified or multiple SUD	8	4.67	2.59–8.41	<0.01*	15.24	54.1	0.03*
Overall	18	3.67	2.31–5.85	<0.01*	664.2	97.4	<0.01*

OR greater than 1 reflect higher prevalence of postpartum depression among women with substance use. OR Odds Ratio; CI Confidence Interval; SUD Substance Use Disorder. * Indicates statistical significance.

TABLE 3 Meta-regressions.

	No. of Studies	β Coefficient	SE	95% CI		*Z*-Value	*P* value
Mean age	12	−0.04	0.07	−0.18	0.10	−0.51	0.61
NOS score	27	0.22	0.16	−0.10	0.53	1.35	0.18
% Married	12	1.23	0.58	0.08	2.37	2.10	0.04*
% Primiparous	14	0.00	0.01	−0.02	0.01	−0.39	0.70

PPD among smokers. It has consistently been reported in the literature that lower socio-economic status has been associated with both higher smoking rates (82) and PPD (9), which could be a mediating factor. Also, tobacco smoking may be highly accepted in certain populations as a normative behavior because it serves as a coping mechanism for the challenges they encounter in their everyday lives (83, 84), which may represent a reporting bias. It has also been observed that exposure to second-hand tobacco smoke is associated with a higher risk of PPD, particularly in women aged 26 to 35 (75). Further research will be needed to analyze this relationship, which has been left out of the scope of this work to the lack of available data.

4.3. Alcohol use

Women with alcohol use during pregnancy presented a 23% rate of PPD, which is significantly higher than the PPD prevalence among the general population, reported around 17% (3). However, no significant difference was found between alcohol users and non-users in our sample, although a clear trend was found (OR 1.88; 95% CI 0.99–3.55; *p* 0.051). Our results differ from the findings of another specific meta-analysis conducted on this topic (23). That study, which presented broader inclusion criteria, reported a significant association between maternal alcohol consumption and the risk of developing PPD (27).

To address such disparities, along with a surprisingly low, non-significant, OR compared to other substances analyzed in this work such as tobacco, it is important to note several facts. First, it is essential to recognize that during pregnancy, alcohol consumption is judged more harshly than in other contexts. Therefore, many women may be reluctant to disclose their consumption during interviews, resulting in inaccurate reporting and contributing to an underestimation of alcohol use in pregnant women (85). Also, the studies included in our systematic review and meta-analysis were significantly heterogenous in their assessment of alcohol consumption across a broader range of categories, including low to moderate levels. For instance, some studies measured alcohol intake during pregnancy as a dichotomic variable (40, 43, 45), while others used specific instruments to assess severity, such as ASSIST (86) or TWEAK (42, 44, 87). Others included a threshold of intake from which alcohol use was reported (39, 41). Although not enough data was found to assess the effect of the amount of the intake on PPD prevalence or OR, this, along with the limited size of our sample, could have influenced the overall risk estimate.

Comorbidity between depression and alcohol use occurs in both directions and common but not fully understood pathophysiological processes have been postulated to explain their co-occurrence (88). For instance, it is known that they may share a common genetic susceptibility (88–90). Additionally, dysfunction in the reward and stress systems has been identified as a potential shared pathophysiology for these conditions (91).

4.4. Strengths and limitations

Our study offers several advantages compared to previous reviews on substance use during pregnancy (8, 10, 11, 25, 92). Firstly, we examine both the prevalence and the relative risk of postpartum depression (PPD) among pregnant substance users. Furthermore, it includes articles reporting on samples from diverse countries across six continents, which enables the analysis of different populations with distinct cultural values and varying levels of socio-economic development, enhancing the generalizability of the results and providing a more comprehensive understanding of the impact of substance use during pregnancy on the risk of PPD. Moreover, our analyzes assess the specific risk associated with different substances, including alcohol (OH), tobacco, and the combination of legal and illegal substances. By considering these categories separately, we can discern their individual contributions to the risk of PPD.

However, this meta-analysis presents also several limitations. First, a significant proportion of the included articles had a NOS score of 6 or

less (38,46%, mean NOS 6.6 ± 0.9), indicating a high risk of bias. Many of the included studies were primarily focused on investigating other primary outcomes, but they included an analysis of substance use as one of the factors examined. Consequently, the available data might not fully capture all the variables relevant to our current study, therefore limiting the precision and reliability of our findings. Second, some studies had small sample sizes of pregnant women actively using substances, further impacting the statistical power of the results. Third, a high heterogenicity was found for all the analyzed variables due to the considerable variability in the samples, the scales utilized to measure PPD, and the different cut-off points employed in various studies. Fourth, our analysis was limited by the absence of available data on potential confounding variables that could influence the observed relationship. Variables such as socio-economic status (92, 93), experiences of obstetric violence (94), gender-based violence (54, 62), lack of external social support (59), obstetric factors (92–94) and pre-existing psychiatric history (54, 62, 95) have been identified in previous studies as potential confounding risk factors within the scope of our investigation. Fifth, the inclusion of the "non-specified or multiple substance use" subgroup introduces an additional layer of complexity and potential bias. While all efforts were made to avoid excluding important evidence from our analysis, this category is inherently heterogeneous, encompassing individuals with varying substance use patterns and profiles, which challenges the interpretation of the findings.

We acknowledge the complexity of research on this topic due to challenges associated with self-reporting substance use during pregnancy, including the fear of stigma or potential consequences (13). However, it is crucial to conduct more studies specifically dedicated to analyzing the relationship between substance use during pregnancy and postpartum depression, using standardized scales and measures of PPD and controlling for all said variables to provide a more comprehensive understanding of the complex interplay between substance use during pregnancy and postpartum depression. Conducting longitudinal studies would enable researchers to examine the temporal relationship, obtain valuable insights into the causal pathways involved and help identify critical periods for targeted intervention.

5. Conclusion

In conclusion, this systematic review and meta-analysis demonstrate an alarming prevalence of postpartum depression among pregnant substance users, extending beyond illegal substances to legal ones. It is particularly concerning to note the high prevalence of PPD among women who smoke tobacco, given that tobacco is a legal and socially accepted substance.

The findings underscore the urgent need for intensified monitoring, early intervention, and tailored support for pregnant women who consume legal or illegal substances. Additionally, there is a clear call for future prospective and high-quality studies to explore further the complex relationships between substance use, mediating factors, and PPD. By addressing these gaps in knowledge, healthcare professionals and policymakers should develop evidence-based strategies to mitigate the risks associated with substance use during pregnancy while improving not only maternal mental health but also considering the offspring's mental and physical conditions.

Author contributions

MP: Conceptualization, Investigation, Methodology, Project administration, Writing – original draft, Writing – review & editing. CA: Conceptualization, Data curation, Writing – original draft, Writing – review & editing, Formal analysis. BP: Data curation, Investigation, Methodology, Writing – review & editing. GS: Conceptualization, Methodology, Writing – review & editing. ES: Conceptualization, Writing – review & editing. MB: Conceptualization, Investigation, Writing – review & editing. RD: Conceptualization, Investigation, Writing – review & editing. IL-Z: Conceptualization, Investigation, Writing – review & editing. JH: Conceptualization, Investigation, Writing – review & editing. ML: Conceptualization, Investigation, Writing – review & editing. AF-R: Conceptualization, Writing – review & editing. CG-R: Conceptualization, Writing – review & editing. MG-T: Supervision, Validation, Writing – review & editing. AC: Conceptualization, Formal analysis, Software, Supervision, Validation, Writing – review & editing.

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Conflict of interest

CA received personal fees or grants from Janssen Cilag and Neuraxpharm outside the current work. CG-R received personal fees or grants from Adamed, Angelini, Cassen-Recordati, Janssen Cilag, Lundbeck, Newron and Otsuka outside the current work. AC received personal fees or grants from Lundbeck, ROVI, and Janssen Cilag outside the current work.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2023.1264998/full#supplementary-material

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Perceptions of perinatal alcohol use and treatment needs in Cape Town, South Africa: a qualitative study

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Background: South Africa has one of the world's highest rates of foetal alcohol spectrum disorders (FASD). Recent evidence also showed that alcohol use during lactation significantly compromises child development in children exposed to alcohol through breastfeeding, independent of prenatal alcohol exposure. This study explored perceptions of perinatal alcohol use and treatment needs in Cape Town, South Africa, to inform the development of an intervention to encourage alcohol abstinence during pregnancy and breastfeeding.

Methods: Individual in-depth interviews (IDIs) were conducted with women who were pregnant with a recent history of alcohol use (n=32) and clinic and community stakeholders (n=16). Interviews were audio recorded and transcribed verbatim. Coding and thematic analyses were conducted in NVivo 12.

Results: Results indicate widespread perception that women know the dangers of drinking alcohol while pregnant with much less known about drinking while breastfeeding. Mixed views were shared about whether women who are pregnant or breastfeeding experience alcohol-related stigma. Participants described contextual factors impacting drinking that include interpersonal violence, lack of support, stress, anxiety and poverty, and drinking being normalised. Finally, participants had mixed views and conflicting knowledge of available resources to support alcohol reduction and highlighted a desire for support groups and the involvement of partners in alcohol interventions.

Conclusions: Findings from this study highlight the need for an alcohol intervention programme that is innovative and tailored to the needs of women who are pregnant or postpartum. It also highlights the importance of including community-based support and partner involvement in these interventions.

KEYWORDS

alcohol use, pregnant women, breastfeeding, perinatal, South Africa

Introduction

South Africa reports one of the highest per capita rates of alcohol consumption in the world (1, 2) of 9.3L of pure alcohol in 2016 (29.9L of pure alcohol per drinker) (3). In a nationally representative sample, current alcohol use in 2014-2015 was reported by 20% of women and among these women, 32% reported binge drinking (defined as consuming 4 or more drinks on an occasion for women) (4). Not surprisingly, South Africa has one of the world's highest rates of alcohol-exposed pregnancies and foetal alcohol spectrum disorders (FASD) because of prenatal alcohol exposure (5–7). A meta-analysis found a prevalence of 13.2% of maternal alcohol use during pregnancy in South Africa (8), higher than the average rate in the WHO African region (10.0%) and globally (9.8%) (5). Binge drinking is particularly harmful during pregnancy, as the resultant rapid increases in blood alcohol concentrations (BACs) increase risk for FASD (9).

While many people reduce or stop drinking after becoming aware of their pregnancy, studies have shown that pre-pregnancy drinking levels are predictive of drinking levels during pregnancy (10). Additionally, even among those who stop during pregnancy, many will return to drinking post-partum. This is a concern as alcohol use during breastfeeding significantly compromises a child's development independent of prenatal exposure (11). In South Africa, drinking while breastfeeding is more common among mothers who drink prenatally, and over 40% of mothers who abstained from prenatal drinking report alcohol use while breastfeeding (11).

Despite the strong evidence for the associations between prenatal and postpartum alcohol use and risk for FASD and compromised child development (11), there is no specific policy to prevent FASD in South Africa (12–14). Additionally, there are few feasible, effective, and sustainable interventions that address prenatal and postpartum drinking while breastfeeding (15–17). While South African studies have identified several factors to consider in developing interventions (18–23), little attention has been paid to women's experiences, beliefs and perceptions of alcohol use and their treatment needs (24). This is important to ensure that potential beneficiaries of the intervention contribute to the intervention design in order to enhance acceptability, uptake and engagement down the line (25). Furthermore, a qualitative study previously highlighted the difficulties that health care providers in Cape Town, South Africa face in addressing alcohol use among pregnant women in antenatal care and the importance of giving voice to their concerns in the development of appropriate interventions (26). Finally a community survey to assess knowledge and attitudes to risky drinking and responses to policy options to address such practices (27) suggests that community stakeholders voices are also important. This qualitative study therefore aimed to explore perceptions of perinatal alcohol use and treatment needs in Cape Town, South Africa, from the perspectives of pregnant and breastfeeding women who drink, and clinic and community stakeholders. This research activity was conducted to assist in the development of an intervention to encourage alcohol abstinence during pregnancy and breastfeeding.

Methods

Setting and recruitment

This qualitative study is presented in line with COnsolidated criteria for REporting Qualitative research (COREQ) guidance (28). We conducted in-depth interviews with women who were pregnant and who reported alcohol use during the current pregnancy. Women were recruited from several communities in the Cape Flats region of the Western Cape Province of South Africa. Additionally, we conducted key informant interviews (KIIs) with clinic and community stakeholders providing services to women who are pregnant and postpartum, to explore their perceptions, experiences, and knowledge about perinatal alcohol use; breastfeeding while drinking; relevant health and psychosocial issues; necessary treatment and services to address these issues; and barriers to linking women to the required services.

For women who were pregnant and postpartum, community-based outreach techniques and snowball sampling were used to market the study and recruit participants. Field staff regularly visited areas frequented by potential participants to enhance visibility and build rapport with community members. To be eligible, women had to (1) be 18 years of age or older, (2) be currently pregnant or delivered within the last three months, (3) report drinking during the current pregnancy or while

breastfeeding, (4) have their own mobile phone, (5) intend to breastfeed for at least 6 months, (6) be able to participate in the interview in English, and (7) voluntarily consent to participate in the study. Clinic and community stakeholders were recruited through two Midwife Obstetric Units (providing antenatal services to women) and a community collaborative board that our team has worked with in past studies.

Procedures

Interviews were conducted by the second author (LEC) and a research assistant who were both female. LEC has a post-graduate degree and more than five years qualitative research experience. Prior to the interviews, participants were asked to provide written informed consent. Interviews with pregnant and postpartum women were conducted within a private space in the community and healthcare clinics. Interviews with clinic and community stakeholders took place at their place of work or telephonically. Interviews lasted up to 60 minutes. Interviews took place between July and November 2021. All interviews were audio-recorded and transcribed verbatim. Participants were reimbursed ZAR150 (~US $8.31 [ZAR18.04/$1]) for their time.

Data analyses

NVivo 12 software was used to manage the qualitative data. Data were analysed thematically using the Braun and Clarke approach (29). We combined a deductive approach to coding based on the research questions with an inductive approach to allow for the identification of emergent themes. The first author (PPW) conducted the initial process of familiarization through a review of transcripts and coding. The first and second author (LEC) discussed the initial framework and individually coded the first two transcripts. Following this, they discussed refining of codes and themes. Intercoder reliability checks were conducted, with a Cohen's Kappa score of 0.80 being obtained. Coding then continued independently for all transcripts. Any coding disagreements were resolved through discussion and consultation with the last author (YW).

Ethical approval

Ethical approval to conduct the study was granted by the South African Medical Research Council's Human Research Ethics Committee and the Western Cape Department of Health.

Results

Three major themes were identified: perceptions and practices of alcohol use during pregnancy and breastfeeding; contextual factors impacting perinatal drinking; and perception of accessibility of resources to support women who drink.

Sample characteristics

We conducted 32 interviews with women who were pregnant with a mean age of 26 years; 31 were Coloured (of mixed-race ancestry) and one participant identified as Black African. A total of 16 clinic and community stakeholders were interviewed. These consisted of researchers, government officials, substance use treatment specialists, clinic-based health care workers and community health workers.

Perceptions and practices of alcohol use during pregnancy and breastfeeding

Knowledge about alcohol use during pregnancy and breastfeeding

There was an overall perception that women continue to drink during pregnancy. Most stakeholders and perinatal participants thought women were aware of the dangers of alcohol use in the perinatal period but continued to drink anyway with only a few thinking continued drinking was due to women being uneducated about the harms.

It is very seldom that we nowadays find that women have never heard that alcohol can be detrimental to the baby. (Stakeholder participant 1)

Alcohol is dangerous for a child because of development for a baby and yes … It's dangerous … It was explained at the clinic….everyone has that information that it's dangerous for a child to take in alcohol but everyone does their own thing. (Perinatal participant 1)

Perinatal participants were able to demonstrate their own knowledge of the harmful effects of alcohol on the foetus, with some sharing their experiences of how alcohol use affected birth outcomes of their own children. Contrary to this, misconceptions associated with maternal drinking exist particularly in cases where women drank alcohol previously and felt there was nothing wrong with their children. Specifically, 22 participants reported they knew the effects of alcohol on the foetus, while one specifically reported not knowing the effects. When speaking about others, comments from six participants suggested that they thought women in the community generally know the impact alcohol has on the foetus, while two thought women might know, five said with certainty that women in the community do not know and eight participant were unsure.

Stakeholders and perinatal participants confirmed widespread breastfeeding among mothers in their communities. While participants described widespread knowledge of the dangers of alcohol use while pregnant, they felt that women knew little about the effects of alcohol use when breastfeeding.

The debate about breastfeeding and alcohol use is very new … And I think that must be added to all intervention programs and

information sessions. Because a lot of women don't realize that. (Stakeholder participant 2)

Stigma related to alcohol use during pregnancy and breastfeeding

Participants shared very mixed views about whether stigma was experienced by women who drink alcohol while pregnant or breastfeeding. On the one hand some stakeholders and perinatal participants shared that these women are treated poorly and experience stigma:

I don't think they will get judged but I think maybe they will lose their friends and they might not be willing to do that. (Stakeholder participant 6)

Contrary to this view, other participants thought that women who continue to drink alcohol during pregnancy or while breastfeeding were treated no differently from women who did not drink, because drinking during pregnancy and the postpartum period is normalised. In total, 14 perinatal participants and six stakeholders thought women who drink alcohol while pregnant or breastfeeding experience stigma, while six perinatal participants and three stakeholders thought this was not the case.

Contextual factors impacting drinking during pregnancy and the postpartum period

Participants described various contextual factors influencing perinatal women's drinking patterns, such as interpersonal violence, lack of familial and community support, stress and anxiety, poverty, and substance use as a way of life.

Interpersonal violence

Violence was described by both stakeholders and perinatal participants as being closely interlinked with alcohol use. Experiences of violence and other forms of abuse were described as the reason for why people drink, in order to forget and also because they feel isolated and unable to share their hardships with anyone. Second, it was thought that drinking in social environments where violence commonly occurs has resulted in the normalization of exposure to violence in the lives of people. In fact, it was pointed out that women can also be the aggressors or abusive towards men even when pregnant as they believe their partners won't retaliate given their pregnancy. Finally, violence was also described as something that is sometimes experienced by perinatal women because of their drinking where women are assaulted because they are 'drunk or unruly'.

Lack of support

Stakeholder and perinatal participants described a lack of familial and community support and lack of emotional, psychological and physical support from romantic partners as influencing drinking behaviour in perinatal women. While they mostly discussed how lack of partner support influenced their use of alcohol, perinatal participants also discussed the support they desire from services in the community.

No, there's no resources … for women in general when you're pregnant or not … I'm alone at times when my husband is at work or wherever then I'm with her alone all the time. And it's sometimes very hard … there's no help for you … No help from police, no help from the clinics. (Perinatal participant 5)

Stakeholders specifically talked about the lack of support perinatal women receive from their partners. They felt that men often believe their role is complete after conception but that they in fact play a big role during pregnancy and after. These participants felt that male partners could play more of a role in supporting their partners to change their alcohol use by reducing their own drinking. Additionally, the pressures and stressors women experience (such as lack of financial support or support with their babies) from these men often lead their partners to drink, feeling trapped in those situations.

Stress, anxiety and poverty

Stakeholders and perinatal participants described the co-occurrence of mental health difficulties and alcohol use among pregnant or breastfeeding women. According to one participant, these difficulties included depression, stress, and psychological trauma.

I think some of them come out of broken homes. Stuff that happened in the past. Childhood injuries, childhood trauma and all that. So, it's a lot of different reasons why they drink. But now they don't drink to just drink, but they drink to solve that problem by creating another problem on top of that … Some of it is very, very bad. (Perinatal participant 20)

Financial difficulties were raised as a prominent stressor, with participants reflecting that women may use alcohol to forget their circumstances. Perinatal women specifically mentioned high levels of unemployment and poverty in their communities. Stakeholders also described how extreme poverty in these communities led to social stress, with alcohol being used to forget this stress.

Alcohol as a way of life

Both stakeholders and perinatal participants described alcohol use during pregnancy and breastfeeding as a way of life in these communities. They noted that alcohol use (including binge drinking) was part of the community culture particularly over weekends where it was viewed as a means of recreation. According to perinatal participants, this culture of binge-drinking over weekends contributed to drinking in pregnancy and while breastfeeding being normalized.

I think, alcohol use over weekends, it's such an ingrained way of life. People really don't know what else to do with their time. (Stakeholder participant 1)

Well, in our community that's - that is something usual … Because everybody does it … Everyone is drinking while they're pregnant. (Perinatal participant 15)

Perceptions of accessibility of resources to support women who drink

Existing resources are limited

Participants had mixed views and conflicting knowledge of available resources for perinatal women who drink alcohol. While some thought there were alcohol intervention support services available, many felt there was nothing available beyond what is offered at antenatal clinics. Among perinatal participants, nine indicated that clinic services were the only resource available while seven stakeholders reported the same. Three stakeholders were however able to describe services beyond the antenatal clinics. Fifteen perinatal participants were unsure or unaware of resources for help or information in their communities. Stakeholders also pointed out that not all primary healthcare clinics where antenatal services are provided had equal available resources to offer support.

The majority of perinatal participants responded 'yes' when asked if the antenatal clinic provides information about effects of alcohol (and other drug) use when pregnant. However, it was evident that much less information was available around alcohol use and breastfeeding. Beyond the primary healthcare setting, stakeholders pointed out that alcohol treatment services were provided by non-government organisations.

Now the problem with that is that not all clinics have got a mental health nurse, because addictions falls under mental health. So you end up referring the person to maybe an NGO or something like that. (Stakeholder participant 3)

Desired additional resources

Perinatal participants expressed a desire for support groups that could be an additional resource for them in the community. In addition to support groups and the need to find ways to provide information about when these services are being offered and how to access them, both stakeholders and perinatal participants raised the importance of including partners in services or interventions for perinatal women who drink.

Discussion

This study described perceptions about perinatal alcohol use and treatment needs in Cape Town, South Africa and highlighted the need for tailored interventions for pregnant and postpartum women. More specifically, findings highlight that knowledge about the dangers of drinking during pregnancy is widespread, with perinatal women being aware of the harm drinking can cause to their unborn foetus. This is in keeping with international literature which demonstrates widespread knowledge about the specific effects of alcohol consumption in pregnancy (30–32), but in contrast to a single SA study. In a study conducted in Cape Town participants were largely unfamiliar with FASD, and their knowledge of the impact of prenatal alcohol exposure was often inaccurate (33).

In this focused local study, personal experiences of alcohol use appeared to influence beliefs about the harms of alcohol during pregnancy. This can lead to misinformation with health implications beyond the woman. This suggests the need for interventions that not only focus on information sharing, but move beyond education to address women's context and attitudes towards anti-drinking messages in order for them to feel heard and be more valued (33, 34).

Innovative approaches are required to help women understand the impact of their drinking on their unborn babies. One caveat of this is that women need to be enabled to become aware of their pregnancies much sooner given the high rates of unintended pregnancies (35) and the critical first stage of pregnancy and alcohol's impact during this earlier stage. Even among women who stop or reduce drinking upon pregnancy recognition, heavy drinking and lack of appropriate vitamins such as folic acid prior to becoming aware of the pregnancy may impact the development of the foetus. Earlier interventions focusing on decreasing alcohol exposed pregnancies are thus crucial to optimize the health of women and their infants.

Findings from this study highlight that far less is known about the impact alcohol may have on breastmilk and breastfed infants. This may be because there is an abundance of evidence for the effects of alcohol use during pregnancy with robust guidelines outlining recommendations, but a paucity of scientific evidence about drinking during breastfeeding and subsequently few recommendations (36). The data thus revealed a need to educate women about harms associated with alcohol consumption while breastfeeding in light of the recent evidence (11), particularly harms around binge drinking among women who are still breastfeeding. There is also a need for more local research on this, to provide compelling local evidence and stories for women so they are comfortable that the evidence that they are presented with is locally relevant and relatable. Therefore, local evidence, stories and narratives need to be communicated to women to convince them of the relevance and suitability of the research evidence for their own lives and context.

Findings from this study also highlight mixed views about whether alcohol use while pregnant or breastfeeding is stigmatized. While some participants thought stigma was experienced, the overwhelming view was that those who do drink during the perinatal period were not treated any differently as drinking during pregnancy and breastfeeding was normalized in many communities. Given the high levels of alcohol consumption in South Africa including among women, and the particular culture of binge drinking, messages to remain abstinent while pregnant and breastfeeding often contradict social norms (33). Intervention programmes therefore need to focus on providing strategies that may lead to changes in how social norms are understood so that abstinence messages are not seen as contradictory to social norms but rather seen as necessary for the health of their infants. Interventions that address community and social norms around alcohol use in other settings by utilizing community reinforcement, advertising or social marketing, social mobilization and broader community-based alcohol prevention programs have shown to impact positively on drinking behaviour (37–41). Similarly, given the findings in the current study, interventions addressing community and social norms around alcohol use in the local

context may impact on women's drinking during the perinatal period.

Finally, this study highlights contextual factors influencing drinking which include experiences of violence, lack of support, stress, anxiety and poverty. Experiences of violence in pregnancy is consistent with research in Cape Town which found that as much as 15% of pregnant women had experienced intimate partner violence ranging from sexual and physical to emotional and verbal (42). The high level of violence during pregnancy was associated with poverty-related factors including food insecurity, mental ill-health, unemployment, unwanted pregnancies and past experiences of abuse (42). Local research has also shown that experiencing violence or aggression is a risk factor for alcohol use in pregnancy (19, 20). Additionally, depression, anxiety, suicidality, food insecurity, relationship dynamics, and past mental health problems were predictors of alcohol and other drug use (19), which supports our findings. In keeping with other studies of women who use alcohol in this setting (43, 44) findings demonstrate that alcohol was used as a way of coping with or managing these stressors and traumatic experiences and emotions.

Mixed views about accessibility of resources and support for alcohol use were also identified with the majority believing there are no resources beyond information provided at primary healthcare. The lack of support and in particular partner support influencing drinking behaviour is consistent with other studies which found that lack of partner support featured as a major factor in pregnant women's drinking (45). Similar to previous studies with women in this setting (43, 44), our findings thus support the need for interventions to address intimate partner violence and associated mental health needs of women who are pregnant and breastfeeding, and to develop community-based networks such as support groups for those who want to reduce drinking. Evidence of partner co-dependency and traditional gender norms in relationships (45) supports the recommendation for couple interventions to include partners with regard to prenatal care, breastfeeding, and drinking.

Findings from this study should be considered in light of its limitations. Firstly, participants who were pregnant were recruited from a mix of communities in the Cape Flats region of the Western Cape province of South Africa. Therefore, the extent to which findings are representative of the total population of pregnant women who use alcohol in South Africa is unknown. Secondly, there may have been social desirability bias particularly from clinic and community stakeholders who may be invested in seeing a programme developed to prevent drinking in pregnancy and postpartum.

Despite these limitations, findings from this study support plans to develop an intervention programme that is relevant to the needs of women who are pregnant and breastfeeding who drink alcohol. It highlights the importance of developing intervention programmes that move beyond education about the harms of drinking in pregnancy to include people's attitudes towards drinking in pregnancy. Second, it highlights the need to provide education around the harms associated with alcohol use and breastfeeding. Third, there is a need to focus on the social norms around alcohol use and the normalization of drinking among perinatal women. It highlights the importance of including community-based support such as peer support groups for perinatal women, referral for intimate partner violence and mental health support and inclusion of partners in the form of couple interventions to enable a supportive environment for having a healthy pregnancy and a thriving child.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by South African Medical Research Council's Human Research Ethics Committee. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

PP and YW conceptualized the study. L-AE-C conducted the qualitative interviews. PP, L-AE-C, ST and YW conducted the analysis and PP prepared the manuscript first draft. FB, BM, WW and CP helped develop and refine the study and all authors revised the draft versions of the manuscript critically. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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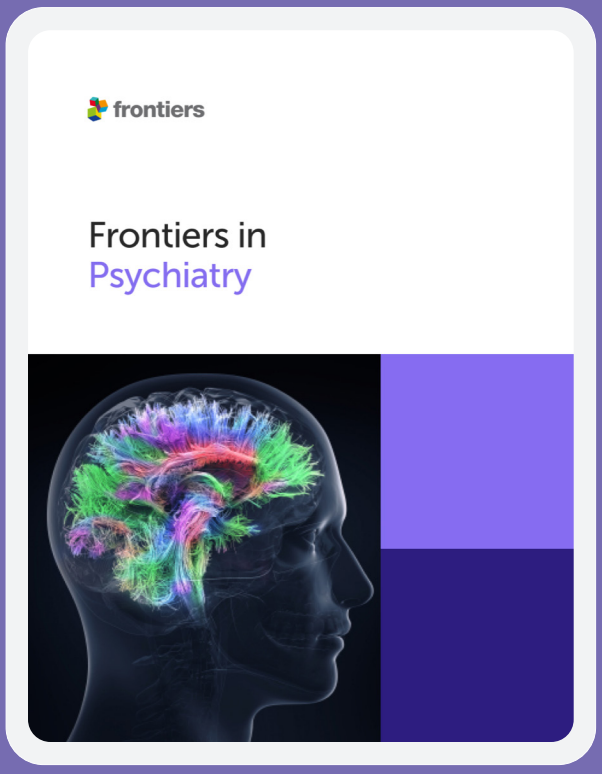

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