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Design of a mobile application for universal screening for women of child-bearing age engaged in comprehensive addiction and recovery environments (WE-CARE) for substance use and women from the general population

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Abstract

Objective: Formative research was conducted to identify barriers to universal screening for alcohol/substance use, depression, and anxiety in women of childbearing age (WOCA,18–44 years of age) drawn from the general population and from women in a residential treatment program for alcohol and/or drug use.

Methods: E-surveys ($n = 467$), focus groups with women aged 18–44 ($n = 30$), and in-depth interviews (IDIs) with healthcare providers (HCPs, $n = 8$) were conducted to create a user-centered design for a mHealth application.

Results: E-surveys revealed that 80% of the women were asked about alcohol use at a visit with their HCP, while 70% were asked about drug use. Only 35% of the respondents indicated an HCP discussed their answers with them. Two focus groups with WOCA revealed minimal to no prior knowledge of risk factors related to alcohol and substance use. Barriers to treatment identified included a lack of readiness to change, cost, minimal social support systems, and a perceived sense of public stigma. In-depth interviews with HCPs revealed not all HCPs use screenings for substance use due to lack of time to conduct a screening, unfamiliarity with standardized screening tools, insufficient training to provide proper follow-up care, no mandates requiring such screenings, and a concern that asking follow-up questions may negatively impact their relationship with the client.

Conclusion: Results from the formative research studies were used to inform the design and development of the WE-CARE app prototype. The prototype, which includes educational content on alcohol and substance use disorders (SUDs), a moderated discussion forum, FAQs, and a Chatbot to encourage participants to make an appointment with an SUD treatment center if indicated, is undergoing pilot testing.

Keywords

Service linkage, digital health, education, mental health, substance use disorder, alcohol use disorder

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Introduction

Cisgender women make up one-third of adults reporting a substance use disorder, while 17% of women between 18 and 25 had an alcohol use disorder.[1] From both alcohol and substance use, they experience more physical consequences than their male counterparts while also suffering a higher risk for comorbid mental health disorders.[1–3] The most common mental health disorders co-occurring with substance use and alcohol use disorder (SUD/AUD) in women are depression and anxiety.[4,5] Of those suffering from depression, 33% also suffer from a substance use disorder.[6,7] Of those suffering from alcohol use disorder, 33% have experienced episodes of major depression.[4]

Physical consequences for females with SUD/AUD include a greater risk of heart disease, relapse after treatment, and overdose when compared with males.[2,3] Other general risks for women pertain to an increased risk for sexually transmitted infections (STIs) through unsafe sexual practices, poor hygiene, and injury.[8,9] The risks for women who are pregnant include a higher risk of miscarriage and the infant's risk of developing fetal alcohol syndrome disorder (FASD).[10]

About half of the pregnancies in the United States are unplanned with the highest risk being for women between the ages of 18–24.

[11] The average time women realize they are pregnant is 5–6 weeks after conception.[12] Although women may not be aware they are pregnant, alcohol use during the first 3 months of pregnancy can result in FASD and impact the baby's health.[13] The indicated health risks for both the women and the infant make addressing the dangers of alcohol and substance use in women of childbearing age (WOCA) a public health concern and priority.

In addition to significant health risks, women perceive and receive more public stigma surrounding alcohol/substance use than their male counterparts.[14,15] Stigma also makes women less likely to seek out treatment.[16,17] Furthermore, state policies regarding the reporting of alcohol/substance use which are intended to help prevent birth defects and complications are instead causing fear such that women tend to under-report use, with only 21% of women reporting their alcohol use during pregnancy.[18] This fear is typically motivated by losing custody of their children as a result of state policies.[19]

Universal screening for WOCA ages 18–44 would address many of these issues.[20,21] In 2018 the U.S. Preventative Task Force (USPTF) supported and acknowledged the need for universal screening with recommendations to implement universal screening for all adults aged 18–25.[21] Similarly, the American College of Obstetrics and Gynecology (ACOG) also recognized the importance of screening by recommending providers screen all pregnant women for substance use.[22] Despite the USPTF and ACOG recommendations, implementation of universal screening still faces multiple barriers, including the general lack of knowledge of both the risks and prevalence of alcohol/substance use, general lack of knowledge of treatment options for women with SUDs, and healthcare providers feeling they are not adequately equipped to provide care for those suffering from a SUD.[14–18]

Screening, Brief Intervention, and Referral to Treatment (SBIRT) is a potentially comprehensive approach for implementation to reduce unhealthy alcohol/substance use and is being looked at as a way to implement universal screening.[5] SBIRT involves asking about alcohol/substance use and the severity of use, followed by a brief 10-minute intervention (motivational interviewing or cognitive behavioral therapy) and ending with a referral to a local treatment center for those identified as at-risk.[23] The evidence for the effectiveness of SBIRT in reducing alcohol use is well supported, specifically when looking at the identification of those at risk and making referrals when SBIRT was implemented in a trauma outpatient clinic.[24] However, the efficacy of SBIRT's "brief intervention" portion for substance use in primary care and emergency departments is still under consideration with a systematic review revealing only moderate supporting evidence.[23]

Novel digital strategies to improve mental health screenings, patient engagement, and referral to treatment show preliminary effectiveness.[25] Mobile applications (apps) can facilitate referrals, deliver educational materials to patients and providers, and enhance communication between patients and providers. Universal e-screenings are suitable for delivery before, during, and after an appointment and could remove many of the barriers associated with HCP time, willingness, or ability.[26] Making the screeners accessible via a mobile phone or laptop can also provide anonymity which would remove the concerns about public stigma. While tailored apps exist to assist HCPs in delivering health interventions related to substance use and mental health that are feasible and acceptable, care must be used to ensure that after screening the woman receives sufficient guidance and support.[27–36]

The goal of this study was to identify the barriers and challenges experienced by women of childbearing age (drawn from the general population and women in residential drug and alcohol treatment programs) and their healthcare providers to implementing universal health screenings for alcohol/substance use and mental health on a mobile device.

Methods

Formative research conducted during the development of the WE-CARE app included a combination of e-surveys, focus group discussions, and in-depth interviews (IDIs) over 8 months to learn more about the barriers and challenges to alcohol and substance use screenings, before

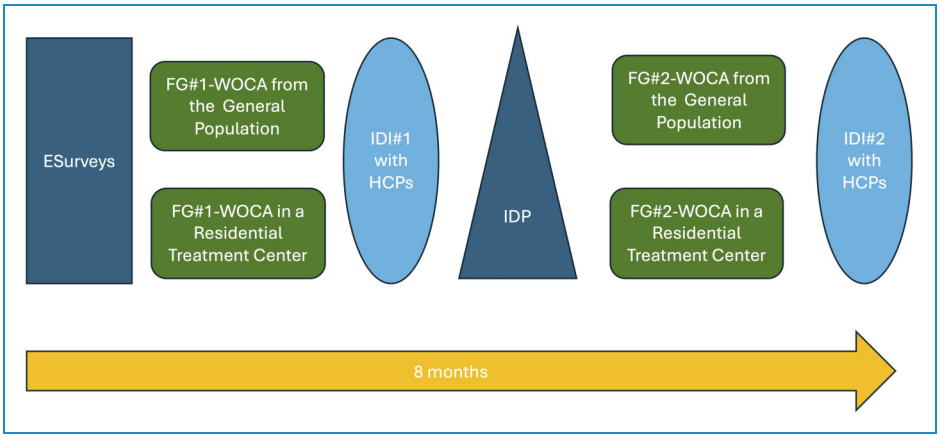

Figure 1. This figure explains the formative research process the we-CARE team utilized including the number of focus groups and in-depth interviews to gather information on previous knowledge surrounding alcohol/substance use, barriers to treatment, and experience with stigma. FG = focus group; WOCA = women of childbearing age; IDI = in-depth interviews; IDP = industrial design partnership; HCPs = healthcare providers.

commencing the design of the mHealth application prototype (see Figure 1 for a schematic overview of the formative research design). Advarra served as the Institutional Review Board (IRB) of record for the study.[37] None of the screening tools are copyrighted. All participants were compensated for their time with e-gift cards.

E-Surveys

An anonymous E-survey was produced and administered through Qualtrics™. The eSurvey was distributed via listservs within a Florida state university and distributed throughout community partners in and around the Tampa region of Florida. The eSurvey questions pertained to how often women engaged in discussion with their doctors regarding their alcohol/substance use and how often women are screened for alcohol/substance use by their physicians. Additional questions queried whether their doctors asked general questions regarding their alcohol/substance use, as well as if they had subsequent discussions with HCP about alcohol/substance use.

Focus group #1 (FG)

Focus Group #1 assessed factors affecting disclosure of alcohol and substance use, factors affecting access and linkage to care, barriers to seeking treatment, previous education and knowledge regarding alcohol/substance use, and attitudes towards alcohol/substance use to provide insight into WE-CARE's design and features. FG #1 included two different population groups: WOCA from the general population living in Central Florida and WOCA in a residential treatment program for SUD living in Central Florida. The two groups were interviewed in separate sessions. The inclusion criteria for focus groups with WOCA in the general population were: (1) must be of childbearing age (18–44 years old); (2) voluntarily consent; (3) be able to read and understand English at an eighth-grade level; and (4) own a smartphone. They were recruited through social media, classroom contact, email, phone, and text. The inclusion criteria for focus groups with WOCA in a residential SUD treatment program were the same as the WOCA in the general population with the addition that (5) the women also be in a residential treatment program for SUD. Women in this group were recruited through collaboration with a local residential treatment center for women with opioid use disorder (OUD).

In-Depth interviews #1 (IDIs)

The IDIs were conducted with HCPs working in community health centers, substance use treatment centers, or private practices. HCPs were identified through relationships with Co-Investigators working in Florida or through the partner treatment center. Inclusion criteria consisted of experience with providing healthcare to women, either in private practice or at community health centers, or with providing substance use treatment in residential treatment centers for women and being fluent in English. The interviews consisted of 10 questions and lasted approximately 30 minutes. The purpose of the IDIs was to identify barriers to care for SUD and screening for women with SUD.

User interface/user experience (UI/UX) design. The UI/UX team used information from the eSurveys and the first round of focus group discussions to better understand the users, barriers to screening for SUD, and barriers to linkage to care for SUD by involving HCPs and WOCA in the general population and treatment for SUD. The core team of researchers also included UI/UX team

members who developed initial design components, including personas, user stories, and user flows. Once the initial design components were finalized, the focus then shifted to developing wireframes (mocked-up images of the future app screens) which were shown to the second focus group and IDI participants for their feedback (see Figure 2 for representative low-fidelity wireframes presented during the Focus Group and IDI sessions).

Focus group #2

The second round of FGs solicited feedback on low-fidelity wireframes and was conducted with WOCA from the general population and with WOCA in a residential treatment center. WOCA from the general population were recruited through convenient sampling strategies. Specifically, researchers advertised the focus group opportunity by sending information to existing contacts via email to non-degree and degree-seeking students in the local community. Recruitment for WOCA in residential treatment centers was executed through emails from an established partnership. Low-fidelity wireframes of the WE-CARE app were used to assess the design aesthetics of the app, relevance of features as they relate to the target population's needs, identify any missing features, readability of content, ease of use of the user interface, and preferred micro-learning topics and delivery methods.

In-depth interviews #2

The second IDI was completed using the same eligibility requirements as the first IDI sessions. HCPs were shown wireframes of the first design iteration and asked to comment on app features.

Demographics

Demographic information was collected via an online survey (for FG #1) or via a paper form (for FG #2 and IDI #2). Meetings for both groups were conducted via Zoom or over the phone and were audio-recorded.

Data analysis. For the focus groups and IDIs, a research assistant (RA) used Zoom closed-captioning and Otter.AI to transcribe the audio recordings. The transcribed audio files were verified by a second RA. A two-stage strategy was used to analyze the FG and IDI data. Descriptive statistics were used to characterize the participants' sociodemographic characteristics. Content and thematic analyses were conducted to identify the types and range of participants' focal concerns related to the research questions.[38] Stage 1 focused on general themes or comments that would immediately impact design (e.g., privacy concerns). Stage 2 was a more in-depth analysis that identified common themes, features participants would like to see in the app, and concerns participants had with using the application. All transcriptions from the first round of FG and IDIs were analyzed using QDA Minor Lite software.[39] The two RAs identified common themes separately to produce individual codebooks. They then consolidated their codebooks into one during a research group meeting to discuss and resolve any discrepancies and re-coded the focus group discussions to match the revised codebook. The remaining authors reviewed the RA's analysis and provided comments to incorporate into the results.

Results

Results from the E-Survey

Participant demographics. A total of 467 electronic surveys were completed with WOCA from the ages 18–44. The majority of the respondents were White (65%), and 36% were Hispanic or Latino (see Table 1).

E-Survey responses. Eighty percent of the WOCA indicated they were asked about alcohol use at a visit with the HCP, while 70% indicated they were asked about drug use. However, only 35% indicated an HCP discussed their answers regarding alcohol and substance use with them. In addition, while only 26% indicated they had completed a written survey about alcohol/drug use, 88% indicated they would do so if privacy was guaranteed. In terms of knowledge-seeking intention, 78% of women reported being interested in watching educational videos to learn more about risky behaviors and information on substance/alcohol use (see Table 2).

Results from Focus Group and IDI Sessions

Participant demographics. A total of four focus groups were conducted, with 16 women from the general population and 14 women in treatment for AUD/SUD (see Table 3). Hispanic women were over-represented in Focus Group #1, compared with national averages, but under-represented in FG#2. Several people selected "More than one race" or "Prefer not to disclose" so the racial diversity may be higher than documented. History of alcohol and/or substance use was not collected from the participants.

In-Depth interview (IDIs). A total of 8 healthcare providers were recruited to participate in the in-depth interviews, 1 was male and 1 did not identify as male or female. The HCPs worked at community health centers or in private practice. All individuals participating in the in-depth interviews were community healthcare providers (Nurse Practitioner, Chiropractor, OB/GYN, Medical Doctor, Director of Adult Residential Services, Access Center Director). Six of the HCPs identified as White, one as

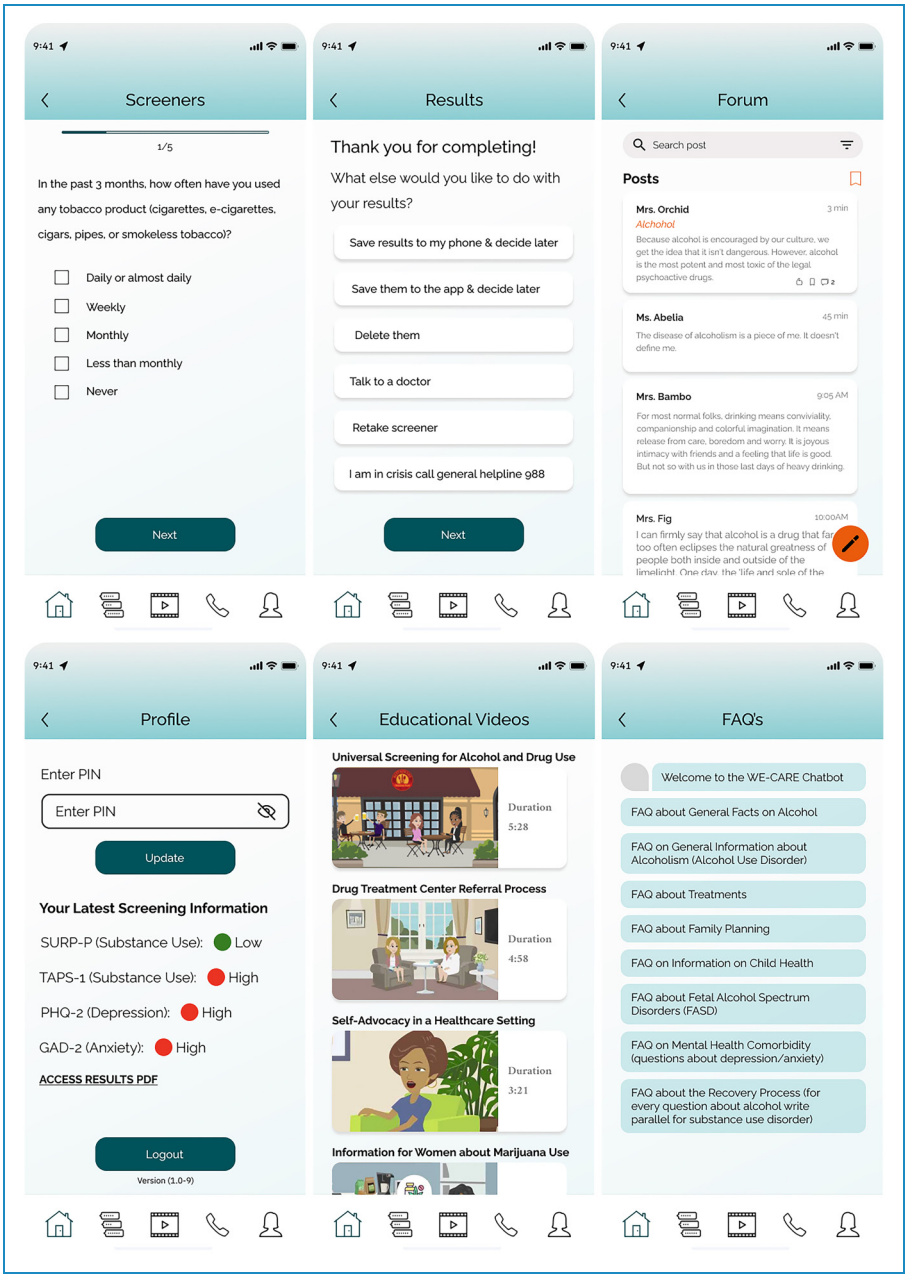

Figure 2. Sample wireframes used in the initial focus group and in-depth interview sessions.

more than one race, and one did not self-identify her race or ethnicity. One person also identified as Hispanic.

Qualitative data from focus group #1. Several themes were identified in reviewing the initial focus group session with WOCA and IDIs with HCPs on barriers and challenges.

Theme 1: Knowledge about Alcohol and Drug Use

Both subgroups of women reported knowing general information about the health risks of alcohol/substance use but did not know specific information about the health risks to the fetus or the women. Participant 2 from the women in the general population commented,

> I think a lot of people know that if you take drugs while you're pregnant, you can have impact on the baby. But as far as like more specific in-depth information, I don't think people would be able to tell you that…

Only 1 person out of the 15 women reported that people should be aware of the specific risks from lived experiences (i.e., adverse childhood experiences)[40] and how those experiences may impact their mental health as an adult. Participants in the general population stated that the content and delivery of the information they currently had access to was useful but not delivered engagingly; the

Table 1. Demographics of e-survey participants: Ethnicity, race, marital status, and age, were collected anonymously from participants in the e-survey.

Ethnic Categories	Values (*N*, % of Total Respondents)
Not Hispanic or Latino	299 (64%)
Hispanic or Latino	168 (36%)
Racial categories	
American Indian/Alaska Native	19 (4%)
Black or African American	83 (19%)
White	304 (65%)
More than one race	23 (5%)
Marital status	
Married	261 (56%)
Living with partner	93 (20%)
Single	75 (16%)
Divorced, separated, or widowed	37 (8%)
Age	
18–25	149 (32%)
26–35	266 (57%)
36–44	51 (467)

scare tactic approach was not useful, and the information was easy to forget. When asked where they currently received their information, participants indicated through the Internet, family, and friends, healthcare offices, community programs, in schools, and with flyers or posters after the women go to the clinic to take a pregnancy test. They were also unsure of the credibility of their sources of information and emphasized they would like to know where and who provides the source information within the WE-CARE application. (See Table 4 for representative quotations on these themes about barriers to screenings and treatment from both Focus Groups).

Theme 2: Pressure to Use

Women in the general population identified the largest source of pressure to use alcohol and substances was derived from family members. *It's definitely social I'm like I'm second generation Cuban. And I just turned 21 On Wednesday, and my family is already planning on getting me like wasted. Entire family, uncles and grandparents and they want to do it with like, you know, their alcohol….* (Participant 7, general population) and *So it was more so like in the private home life that you will kind of see like the overconsumption of alcohol, and it was passing out or using a lot, but you could finish it and you know, they function* (Participant 3, general population). Women in substance use treatment also identified social pressures outside the immediate family members such as *I was like such a good girl until I moved away to college and then once I started partying I was something a switch flipped. And it's the only way I know how to describe it. Like once I once I crossed a line, I had crossed that line. And I had no control over it wasn't just partying anymore* (Participant 2, residential treatment).

Theme 3: Barriers to Screening and Seeking Out Treatment

Some of the barriers to screening and seeking treatment identified by both populations of women included personal lack of willingness to change, lack of a support system to help them stop using, lack of insurance to pay for treatment, fear of stigma from others, and fear that their baby or children would be taken away from them.

Women were asked to consider what would be the barriers to anonymous E-screenings. Both women in the general population and women in treatment were worried about the privacy concerns of the app, making comments such as, "*That'll be covered by HIPAA [the Health Insurance Portability and Accountability Act of 1996]. Well, will that app or will the HIPAA laws apply to that*?" (Participant 3—general population), and "*Then even if you do manage to get the app to be private, and then you get to tell patients that this is totally private*" (Participant 2—general population).

The women in the general population also reported a lack of internet access just as frequently as concerns about privacy. Some additional barriers to using an app included wanting to know they were getting credible information from a "real person" (i.e., someone in the field) and lack of time to answer the questions. A couple of individuals in the focus group with WOCA from the general population reported fear that the app may not provide individualized options for different people suffering from substance use, using statements such as, "*That's me isn't but it might work for somebody like participant one, it might work for participant two, so I think it's good to have an arsenal of options" (Participant Number Unknown). WOCA in the general population also mentioned fear of the stigma surrounding women receiving help for substance use and what others may think with comments such as, "…even if you do that's a public place and like if you're using the library's computers anyone could look over your shoulder that's embarrassing because stigma…*" (Participant 3—general population).

Table 2. Esurvey questionnaire.

Question Topic	Yes	No	Don't Know/No Answer
Have you ever been asked about alcohol at a doctor's appointment?	375 (80%)	84 (18%)	8 (2%)
Have you ever been asked about drug use at a doctor's appointment?	325 (70%)	127 (27%)	15 (3%)
Do you feel you can talk to HCP about alcohol/drug use?	363 (78%)	63 (13%)	40 (9%)
Have you ever completed an alcohol/drug use universal screening e-survey?	123 (26%)	328 (70%)	9 (4%)
If your privacy was guaranteed, would you complete universal screening e-surveys?	413 (88%)	49 (10%)	5 (1%)
Are you interested in watching short videos about risky behaviors, universal screenings, and treatment options?	363 (78%)	92 (20%)	12 (2%)
	Always	Sometimes	Never
How often does your doctor talk with you about alcohol and/or drug use during your appointment?	163 (35%)	275 (59%)	29 (6%)
How often does your doctor talk with you about sexual history or behavior (condom use/birth control) during your appointment?	145 (31%)	283 (61%)	35 (7%)

Note. This table shows the frequency of responses to each question we asked WOCA on an E-Survey sent out before the development of the mobile app.

Table 3. Focus group demographics.

	Focus Group #1		Focus Group #2	
Ethnic categories	WOCA from the general population (*N*, % of total respondents)	WOCA in substance use treatment (N, % of total respondents)	WOCA from the general population (*N*, % of total respondents)	WOCA in substance use treatment (*N*, % of total respondents)
Not Hispanic or Latino	5 (56%)	5 (83%)	7 (100%)	7 (87.5%)
Hispanic or Latino	4 (44%)	1 (17%)	0 (0%)	1 (12.5%)
Racial categories				
American Indian/Alaska Native	1 (11%)	None	None	None
Black or African American	1 (11%)	None	1 (14%)	1 (12.5%)
White	5 (56%)	5 (83%)	3 (43%)	6 (75%)
Asian	None	None	1 (14%)	None
More than one race	2 (22%)	1 (17%)	None	1 (12.5%)
Unknown or not reported	None	None	2 (29%)	None

Note. This table shows the ethnic and racial distributions of participants in the four focus groups.

During the IDIs, HCPs (IDI#1) also alluded to the women's fear of receiving stigma from others regarding treatment when she stated screenings should be, "…*made easy, and it also needs to be non-threatening*". HCPs also reported barriers to administering screenings such as a lack of time to administer formal screenings for substance use, a lack of mandate from the government to give formal screenings for substance use, and also a lack of

Table 4. Barriers and challenges related to using a mHealth application for alcohol/substance use screenings.

Barrier	General Population Focus Group	Substance Use Residential Treatment Program Focus Group
Privacy/Anonymity Concerns	*"I think concealment would be a good thing. Me? I don't care. I'm pretty open about things like hey, listen, but other people might not want his family know so maybe if there's a feature where if you choose to have it be concealed the app does it just looks like [indiscernible]. And then if notifications pop up, maybe it pops up as something else." (Participant 3)* *"And Google is always freaking watching you. Like, I don't want to... download this app. You know, you screen it'd be so easy this way. And now all of a sudden, Google's giving me all these ads for like, treatment centers and stuff..." (Participant 3)* *I would want it to be able to connect me with somebody that could help me like straight away and just like easily and discreetly and affordably. (Participant # unknown)*	*I would definitely do it because it'd be between me and nobody else would know that I was doing it because I wouldn't want you know, you know what I'm saying? It's kind of being able to have my dirty secret or, you know, I would feel more confident as opposed to reaching out to the community and or a medical professional because it's kind of like just between me and this... where I would feel 1000 times more comfortable even opening that app because I would feel safe and secure there because it is anonymous. (Participant 2)* *The government, just they're always watching. (Participant 3)*
Lack of Internet Access (i.e., no easy access to WIFI, limited data on their phone)	*"Yes, absolutely. Not everyone has access to Wi Fi and much less stable Wi Fi or a computer or a phone that can use data or Wi Fi ...' (Participant 4)*	*If you can get like an app where you don't have to download on Wi Fi or something else. I do not know if it's a real thing but, you know, sometimes even doctor's offices don't have or don't let you use their Wi Fi. (Participant 1)*
Stigma Concerns	*"I feel like there would be a stigma on drinking in general, like socially viewed. You know, if you're pregnant, you're supposed to be taking care of your body... So I feel like socially, it's viewed as, like a negative in a negative way where I feel like in general, maybe yeah, a glass of wine isn't that bad, but... socially viewed like women just drinking period, like when they're pregnant is like a no." (Participant 4)*	*They are going to find out because at the doctor's because they drug test. So then you don't go to your medical appointments because ... (Participant 3)* *It's one of those things where sometimes you're too ashamed to even mention something in front of a professional right? (Participant 1)* *But so doctors treat you like shit if you were a drug addict. Yeah, and they make you feel like a piece of shit. (Participant 3)*
Credibility of Educational Resources	*"It kind of takes away from the accessibility of it, but I think the only way that I would go onto an app store and download an app is if it was, like presented to me from an actual clinician... but then that adds, if I'm going to a clinician to get that app recommendation, then the accessibility issue is still there. '(Participant 2)* *"As well as just schools maybe like, like also like normally clinicians giving that as a resource but having it just be like a fundamental resource in outlet for colleges, universities, we know even high schools, middle schools even I mean, just schools in general..." (Participant 4)* *'It will be limited because an app should not be your one stop shop for all of your mental and psychological needs. But I think it is a good starting point.' (Participant 3)*	*You know and it wasn't really talked about at school, and it certainly wasn't talked about in my home and it should have been. I feel like when you go to like the doctors and stuff and you have to get on pain medication, I feel like they should definitely tell you the risks. of like getting addicted to the pain pills, because I hear a lot of people wind up addicted on the pills. (Participant 2)* *I would hope that your OBGYN would would maybe educate you a bit you know, your OB GYN, you can say they're naive, they're new to this. (Participant 2)* *But you don't know they are believable or not with all these stuff on the internet. (Participant 3)* *...community programs to like resources like the 211 where, you know, you kind of contact them*

(continued)

Table 4. Continued.

Barrier	General Population Focus Group	Substance Use Residential Treatment Program Focus Group
	Any sort of like diagnostic or treatment medication or referral for any sort of freedom. I want it to be done face to face with like, even on the phone, just like the telecommunication sort of thing, or else I'm not going to believe it. I'm not gonna think it's trustworthy. If it's just some random generator saying like, you answer these questions a certain way you have depression, I'm not gonna buy it'. (Participant 2)	*and tell them what you're going through where they kind of facilitate and branch you in different directions, which is a good resource staff. Not everybody knows about some of these resources. I think for someone to overdose and come into your hospital and you to be a doctor and not setting that person out with at least some sort of resource is unethical. (Participant 1)*
Lack of Time (i.e., time to download and take screener)	*"If I am a person who is struggling with a substance abuse problem, I'm not going to take time out of my day to download an app. I'll just find something random on Google if I do want to do anything about it. So I'm not going to take the time out of my day to get an app much less follow up with anything that the app tells me." (Participant 4)*	*N/A*
Cultural Sensitivity Concerns	*Yes, like earlier when I was talking about like having more screening to like, find, do the referrals that fit, like things like you know, your zip code, so it's in your area, what's your primary language? How do you identify and then you can have like, more person centered. (Participant 2)* *We didn't really discuss that whole, like queer women at all. And I think that's another like they have special needs, and also transman as you get pregnant. You know, like in the trans and gay community, like there's, there's a lot of like substance use, you know, issues and stuff and like, there's just like extra special needs like in the LGBT plus community. (Participant Unknown)* *"I don't think an app has enough, has everything in the arsenal. I don't know what's going to work for what different people could be like for sure they could be I already know I got substance abuse... but it might work for somebody like participant one, it might work for participant two, so I think it's good to have an arsenal of options." (Participant 5)*	*N/A*
Lack of a Variety of Treatment Options and the Costs	*"Connect to services, and then I mean, I've never made it before. So I don't really know what the limitations are, but when like, you're in that referral stage or like, the common things that people need... you might be getting medications when you need bloodwork, okay, what other common things do they need if they're women like who are childbearing and they might need to go see an OBGYN?" (Participant 2)*	*Sometimes people don't have like six months to go to a program that house bills, kids, anything, a job that they can't leave? (Participant 1)*

knowledge of appropriate referral services depending on screening results. Another concern was that asking questions regarding their client's substance use may impact their relationship with the client and lead to distrust. They did not want to lessen the rapport they had built by asking sensitive questions about drug and alcohol use.

After analyzing the initial focus group and IDI themes, the following features were included in the mobile app design to be used with the FG#2 and IDI#2 discussion groups: E-Screenings for substance use and mental health, a moderated forum for women to ask questions of a licensed social workers and peers, a list of frequently asked questions (FAQs) for access to evidence-based information, educational microlearning videos on alcohol/substance use and related information, resources (information on treatment centers and hotlines to call) for those suffering from anxiety/depression, and encouragement to make an appointment with the partnered treatment center to receive substance use treatment After discussion with our Expert Advisors and academic Co-Investigators, four screeners (the Substance Use Risk Profile-Pregnancy Scale (SURP-P) if the woman was pregnant; Tobacco, Alcohol, Prescription medications, and other Substance (TAPS1) for alcohol and substance use; Generalized Anxiety Disorder 2-item (GAD-2) for anxiety and Patient Health Questionnaire-2 (PHQ-2) for depression) were provided withn the app and all participants had to complete all the screeners.[41–44] The SURP-P is one of the few validated screeners for SUD in pregnant women[8] and the PHQ-2 and GAD-2 are used in the Center for Disease Control's Household Pulse Survey.[45] The TAPs-1 was selected due to its brevity, and good to excellent validity for detecting tobacco, marijuana, and alcohol use..[46] (See the Supplemental Materials for the questions used in each instrument).

C. Qualitative Data from the Focus Group #2 and In-depth Interviews #2

The second focus group and second round of IDIs gathered feedback on the wire-frame design of WE-CARE produced by the core researchers and UI/UX team. Specifically, the questions focused on the aesthetics of the design, relevance of features, missing features, readability of content, ease of use, and topics used in the micro-learning materials. The focus group was set up in the same way as the focus groups with 2 sessions, one session being with women in the general population and the other being just the women in a residential substance use treatment center. HCPs were interviewed one-on-one with the RA.

FG2—Theme 1: Thoughts on using Mobile e-Screeners

Women were asked if they had used a mobile application to complete a screener for substance use or an application like WE-CARE. Results differed between the women in the general population and the women in substance use treatment. Six out of seven women in the general population reported no previous use (85.7%), with 1 not reporting, while four out of eight (50%) participants in a residential SUD treatment program reported no previous use. Following up with the women in residential treatment for substance use, the applications they had used did not appear relevant as three of the four did not remember the name of the previous app and only 1 participant commented that the app was helpful. In addition, it sounded like the app was for coordinating their stay at the residential treatment center, not for screeners, as she stated "*It provided me with the information I needed to see, um, like how many days I needed to stay here and stuff like that. It provided me with the information that I needed. So yes, it was helpful"* (Participant 2—residential treatment).

Comments were made by both groups with regards to when they would be most likely to use this app, with participants reporting they would be likely to use when experiencing a relapse, in recovery from substance use, to receive general information on substance use and the options, at the beginning of pregnancy to ensure the baby's health, and to refer to a friend whom might be at risk for a substance use disorder.

FG 2-theme 2: home screen and login

The WE-CARE team solicited feedback on the low-fidelity wireframes starting with the login and home screen pages. Overall, the onboarding pages containing general information on each feature of the app were well-liked by both groups. Participants thought the onboarding was straightforward, simple, and well-defined. Participants liked the option to be anonymous by creating a nickname for use in the forum component of the app. One woman liked the name, WE-CARE, and two women reported they liked the WE-CARE statement describing what WE-CARE is and what it is used for. Regarding the anonymous feature, the participants were asked if they would have difficulty in coming up with a unique nickname to use when posting on the forum or in the app, which 13 out of 15 participants in the focus group felt would not be difficult to do.

Upon completion of the onboarding, the overall aesthetics and features of the home screen were discussed in both focus groups. Participants were generally satisfied with the home screen layout, with some specific comments about enlarging button sizes. The top four most frequently anticipated useful features to access from the home screen were the E-Screeners ($n = 9$), FAQ ($n = 9$), National Helpline numbers ($n = 8$), and microlearning videos ($n = 6$).

FG 2-theme 3: E-Screeners

Women in both groups liked the E-Screeners, specifically commenting they were "*easy to navigate*" (Participant 8—residential treatment) and "*the amount of questions isn't overwhelming*" (Participant 1—general population). A common response in the FG with the women in the

general population was the desire to have additional screening for domestic violence, reporting their concern that some individuals may be going through that in addition to struggling with substance use or mental health issues.

Participants were shown wireframes that individuals who would identify as elevated risk for substance and/or mental health concerns would see and the path for those who identify as low risk. Women in treatment for substance use expressed they would all want to have the option to enter their phone number or email for the treatment center to get back to them and six of the eight wanted to be provided with numbers for multiple local agencies they could call. Women in the general population made comments on entering their number and having the treatment center call them with four (57.14%) commenting they liked that feature, three (42.86%) specifically wanting crisis lines, and two (28.57%) wanting an option to talk with the Chatbot before the treatment center contacts them. Some participants expressed privacy concerns about someone asking about the results of the screeners, and all participants in both groups reported they would want to use biometric security (i.e., Face ID, fingerprints) or a passcode for privacy protection.

Participants in both populations discussed what they would like to do with their results. All women in the SUD treatment program reported they would share their results with their healthcare provider and five (71%) in the general population would do the same. Participants were asked if they would like to provide their GPS location or zip code to get local resources based on their screening results, and all participants in both preferred the option to enter their zip code rather than allowing the app to determine their location through GPS tracking.

FG-2-Theme 4: educational materials

The 1–5 minute microlearning videos were overall well-liked with participants commenting they liked the format of having the videos categorized under topics in a list formation. Results were mixed between FGs regarding the delivery of the content. All participants in treatment with SUD liked the videos being cartoons, while some participants within the general population said they would like the videos to be more realistic ($n = 1$) or would like a mixture of realistic and cartoon formats ($n = 2$). Both groups felt strongly they would like to see the videos tailored to their demographic ($n = 13$). When the participants were asked what topics they would like the videos to cover, no single topic stood out but participants reported favoring topics such as information on treatment centers for SUD treatment, sexually transmitted diseases, how substance use impacts the baby, information on Plan B, general information on substance use, the interaction of substance use with problems associated with mental health and domestic violence, child protection court, and resources out there specifically for women who are parents.

FG-2-Theme 5: FAQ section

How the FAQ information was presented was almost unanimous between groups with 14 out of 15 of the women desiring a Chatbot to engage in natural language conversation, rather than delivering a list of topics and answers for the participant to scroll through.

FG-2-Theme: 6 moderated forum

Participants were presented with wireframes depicting what the forum would potentially look like and were asked their general thoughts. Participants liked that the forum would be interactive with users having the ability to post anonymously, that the forum could be broken down by topic with different sections for different topics, and felt the forum made them feel more connected to care when it was moderated by a healthcare provider. Participants also discussed who they would like to respond to their posts, and 10 out of the 15 (66.67%) expressed wanting both healthcare providers and peers to respond. In addition, participants felt the moderator should have the ability to delete posts they find repetitive or inappropriate ($n = 9$) and felt rules needed to be established ($n = 7$).

D. Features Developed as Result of Formative Research

Upon completion of the second focus group and IDIs, the wireframes were revised to incorporate as much of the feedback as possible and to design the prototype for testing. The prototype design will include multiple new features such as a pin code to protect the user's anonymity, customized microlearning videos, and a licensed counselor to respond to moderated forum questions. The following additional features will be considered in the final prototype design:

1. A risk assessment (elevated risk or low risk) will be immediately provided to the participants and the women can store the results within the app or on their phone. If the participants are assessed as elevated risk for alcohol or substance use, they will be encouraged to leave their phone numbers so the treatment center can call back within 24–48 h to provide a standardized intake. Alternatively, the person could call a dedicated phone line and reach someone at the treatment center directly, or they could call a crisis hotline. If the person is NOT at elevated risk for alcohol or substance misuse but does score high for depression and/or anxiety, they will be presented with a series of crisis hotline numbers to call, as well as contact information for mental health treatment centers in their local county. Given the concerns about domestic violence expressed in the focus groups, we plan to add a domestic violence hotline in the next round of revisions to the app design.

2. The encouragement to make an appointment with the treatment center will also be provided by a licensed social worker (LSW) rather than a Chatbot. The LSW will check the app logs each morning and inquire with women who had an elevated-risk assessment as to whether they had contacted a treatment center. The LSW will use motivational interviewing tactics to see where the women are in seeking treatment and provide reassurance if they have concerns regarding making an appointment.
3. To address concerns about a lack of Internet access, the app will be designed so that the women can take the screeners and review the educational content without wifi access.

Discussion

WE-CARE prototype app will be designed to utilize anonymous e-screening from a mobile phone for alcohol/substance use, depression, and anxiety to help identify women at risk and provide education on risky behaviors and treatment options. SAMHSA recommends the use of the SBIRT method to combat the problem of lack of universal screening.[5] WE-CARE incorporates the screening components of the SBIRT method and addresses potential stigma concerns by providing anonymous universal screening to women from ages 18–44.[5] WE-CARE also addresses the need for brief intervention and referral to treatment by incorporating motivational interviewing and by partnering with a local SUD treatment center to provide a "warm digital handshake" (e.g., a referral to a treatment center) for those who, based on the answers to their screeners, are indicated at elevated risk for an AUD/SUD. Individuals who are at risk for depression or anxiety will be given recommendations to local mental health treatment centers, customized to their geographical location.

To support the need for this app, we gathered information through e-surveys on the frequency with which individuals were asked about alcohol/substance use by their primary HCP. The majority reported that while they were asked about their daily or weekly alcohol or substance use, they typically did not discuss the results or responses with their HCP further during their appointment. Many focus group respondents also reported that if their privacy was guaranteed they would be willing to answer a brief e-survey regarding alcohol/substance use and would be interested in watching brief videos related to risky alcohol/substance use, thus supporting WE-CARE's design to provide e-screeners and educational videos. The focus groups and IDIs further supported the implementation of educational videos by reporting minimal knowledge about risky levels of alcohol or substance use. HCPs reported they give their patients educational materials but not specifically ones on alcohol/substance use, noting that WE-CARE could fill in this gap.

The WE-CARE team wanted to understand the barriers and challenges of childbearing women in the general population as well as women in substance use disorder treatment to help inform the application design. This study confirmed that several barriers hinder the widespread implementation of universal screening for SUD in WOCA. Lack of knowledge on alcohol/substance use,[47,48] and a lack of screening and/or follow-up in primary care settings prevented many WOCA from receiving treatment and preventive services.[49–51] In addition, stigma, lack of social support, costs, and the need to be "ready" for change were identified as major barriers. This research supports the findings that women need more information and options to personalize their follow-up care. The revised prototype design will combine a variety of solutions with anonymity to allow the woman to take a proactive role in her treatment.

Healthcare providers had similar concerns as the women and gave the WE-CARE team directions to focus carefully on the wording used in the app to make the app feel non-threatening. In previous research examining the connection between stigma and reproductive health services, women reported experiencing perceived and direct stigma from HCPs.[52] Perceived stigma refers to the stigma women expect to receive when they express substance use, direct stigma can be seen through the use of stigmatizing language, such as using words like "addict" or "dirty."[53,54] Healthcare providers are not at fault for unintentionally expressing stigma as they also suffer from a lack of knowledge on how to properly care for substance use patients and reasons why the women might use (i.e., past trauma).[55] The WE-CARE team will develop a training video for HCPs to inform how stigma can be addressed in the clinic and to provide brief education on how to avoid expressing stigmatizing language.

App development will address stigma and privacy features in response to these concerns by making the app anonymous and creating a PIN code for access to the app. To protect the woman's privacy, a four-digit PIN will be required each time she opens the app, and all messages delivered to the woman's phone will be phrased neutrally (e.g., "Please see the WE-CARE app for an important message"). In addition, to respect HIPAA guidelines, we will not enable the sharing of the screening results directly with the healthcare provider. Instead, the woman will be able to save the results to her phone in PDF format, and then upload the file to her electronic health record or show it to her HCP in an in-person meeting. In addition, during sign-up, the user will only need to input their phone number if they want the treatment center to reach out to them and input a zip code if they want to see a list of local mental health facilities. At no time will the app collect the woman's personal identifying information.

Feedback from the focus groups and IDIs regarding features on the homepage, including easy access to educational videos, national and local helpline numbers, and e-Screener

questionnaires will be incorporated. A majority of the women desired the FAQ to be interactive meaning they can ask the application questions, but for the prototype, WE-CARE will use a FAQ list with questions to click on and open a new screen with an answer. In future iterations of the app, we plan to expand and make a natural language Chatbot that is more advanced and free-form.

The moderated discussion forum will also be moderated by an LSW rather than a Chatbot, in recognition that the Chatbot was not sophisticated enough to give clear and concise answers to questions or to assess what was written for inappropriate language.

A survey of available apps at the iTunes or Google Play store revealed no apps offering the same range of resources and autonomy after offering anonymous universal screenings. The WE-CARE app will give the women both the results of their screenings for substance use, anxiety and depression and the knowledge as to what to do with that information. The woman can decide whether to call a hotline, access a treatment center, talk to her doctor or do nothing. The REFRAME app has some similar features, but the initial questions were not from a validated screening tool, a risk assessment is not offered, and the focus was on recovery from alcohol misuse, not on identification of problem drinking or drug use, or comorbid mental health issues. Other potential competitors would be Woebot and the website, SoberMom Squad, both of which are also focused on recovery support. When the WE-CARE app is ready for commercialization we will rescan the app stores and identify the most viable strategy for commercial success.

Finally, the initial prototype will not provide information on promoting wellness visits and medication information, as that was beyond the scope of the original proposal. Wellness visits and medication information could be features to consider for furthering the WE-CARE application in future iterations.

Limitations

There were several limitations to the study design. The most significant of which are (1) generalizability, (2) self-report, (3) race/ethnicity, and (4) possible socioeconomic bias. For this stage of usability testing, the population was limited to women between the ages of 18–44 who lived in central Florida, as Benten was partnered with a substance use treatment center in the area. As such, this sample population may not be generalizable to individuals living in other regions of the USA. In addition, the survey relied on self-reported data that may be subject to recall or social desirability bias. Hispanic women were over-represented in the general population focus groups (75%) and under-represented in the residential treatment focus groups (14.29%), and there were low numbers of African-American participants in both groups (12.5% and 7.5% respectively). Finally, this preliminary study doesn't deeply explore factors like cultural differences, socioeconomic status, or education levels that might influence screening practices or treatment-seeking behaviors. Future development efforts will be expanded to a national focus with specific attention being devoted to recruiting individuals representative of the subpopulations under study.

Conclusion

The results from the focus groups and interviews were used to inform the design of the WE-CARE prototype and to gather knowledge on barriers to implementing universal screening for SUD and how an anonymous digital solution can help alleviate those barriers. In utilizing an app to provide screening and referral for AUD/SUD treatment, the main concerns expressed by both the HCPs and WOCA revolved around the stigma surrounding women suffering from AUD/SUD, maintaining privacy, and ensuring the validity of the information provided. Some of the main barriers identified by HCPs included concerns about lack of time to administer the e-Screenings, lack of mandate, and lack of knowledge of options for care once the results are received. These concerns will be addressed in the redesign of the WE-CARE prototype, which will then undergo further development and testing.

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Data availability: All data generated or analyzed during this study are included in this published article or will be made available upon request.

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