Women Empowered to Connect with Addiction Resources and Engage in Evidence-based Treatment (WE-CARE): A Usability and Feasibility Study of a Mobile Health Application for the Universal Screening of Alcohol, Substance Use, Depression and Anxiety.

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Table of Contents

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Abstract

Background: Women of childbearing age (WOCA,18-44 years of age) face multiple barriers to receiving screening and treatment for unhealthy alcohol and substance use, depression, and anxiety, including lack of screening in the primary care setting and lack of support in accessing care. The Women Empowered to Connect with Addiction Resources and Engage in Evidence-based Treatment (WE-CARE) mobile app was developed to test universal screening with WOCA and linkage to care after an assessment for substance use disorder (SUD).

Objective: In this study, we aimed to investigate the feasibility and acceptability of providing anonymous screening instruments for alcohol and substance use, as well as depression and anxiety, for women of childbearing age through mobile phones.

Methods: We used Agile development principles based on prior formative research to create an alpha version of a WE-CARE mobile health application that was piloted with WOCA (N = 30) who resided in one of six counties in Central Florida. WE-CARE included screening instruments (for substance use, depression, and anxiety), a moderated discussion forum, educational micro-learning videos, an FAQ section, and resources for linkage to treatment. Individuals were recruited using flyers, academic listservs, and a commercial human subject survey company (Prolific). Upon completion of the screening instruments, women explored the educational and linkage to care features of the app and filled out a System Usability Scale (SUS) to evaluate the mobile health app's usability and acceptability. Post-pilot semi-structured interviews (n = 4) were conducted to further explore the women's reactions to the application.

Results: Seventy-seven women downloaded the application and 30 completed testing. WOCA gave the WE-CARE app an excellent SUS score of 86.7 + 12.43 (SD). Out of the 30 participants (African American (N=1, 3.3%), Hispanic (N=6, 20%), more than one race (N=5,16.7%), White (N=14, 46.7%), Unknown (N=7, 23.3%)), 60% (n=18) had results indicating elevated risk for substance use, 50% of these 18 (n=9/18) indicated elevated risk also for anxiety or depression, and 61% (n=11/18) indicated elevated risk for substance use and/or anxiety or depression. Participants reported that WE-CARE was easy to navigate and use but they would like to see more screening questions and more educational content. However, linkage to care was an issue, as none of the women identified as 'at-risk' for SUDs contacted the free treatment clinic for further evaluation.

Conclusions: The mobile health application was highly rated for acceptability and usability, but participants were not receptive to seeking help at a treatment center after only a few brief encounters with the application. The linkage to care design features was likely insufficient to encourage them to seek treatment. The beta version of WE-CARE will include normative scores for participants to self-evaluate their screening status compared to their age- and gender-matched peers and enhanced linkages to

care features. Future development will focus on improving engagement to change behaviors and assess readiness for change.

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Abstract

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M**ethods:** We used Agile development principles based on prior formative research to create an alpha version of a WE-CARE mobile health application that was piloted with WOCA (N = 30) who resided in one of six counties in Central Florida. WE-CARE included screening instruments (for substance use, depression, and anxiety), a moderated discussion forum, educational micro-learning videos, an FAQ section, and resources for linkage to treatment. Individuals were recruited using flyers, academic listservs, and a commercial human subject survey company (Prolific). Upon completion of the screening instruments, women explored the educational and linkage to care features of the app and filled out a System Usability Scale (SUS) to evaluate the mobile health app's usability and acceptability. Post-pilot semi-structured interviews (n = 4) were conducted to further explore the women's reactions to the application.

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Conclusion: The mobile health application was highly rated for acceptability and usability, but participants were not receptive to seeking help at a treatment center after only a few brief encounters with the application. The linkage to care design features was likely insufficient to encourage them to seek treatment. The beta version of WE-CARE will include normative scores for participants to self-evaluate their screening status compared to their age- and gender-matched peers and enhanced linkages to care features. Future development will focus on improving engagement to change behaviors and assess readiness for change.

Introduction

Alcohol and substance use can have devastating health consequences for women. The physical health risks to women who engage in heavy alcohol and substance use include increased likelihood of injury, overdose, organ damage, and STDs due to unsafe sex practices[1]. In addition, binge drinking (defined as 4 or more drinks on one occasion in women) has reached epic proportions (44%) in young women in the US[2,3], and the rate is increasing rapidly in women over the age of 35[2,3]. The number of women dying of opioid overdoses has also increased by 260% between 1999 and 2017[4]. Substance use during pregnancy can also elevate the risk of miscarriage, fetal alcohol syndrome, and birth defects[5]. The US Preventative Task Force (USPTF) reported that about 50% of US pregnancies are unplanned or unintended, with women between the ages of 18-24 facing a higher risk of unplanned pregnancies[6]. As such, alcohol and substance use during pregnancy can pose a combination of risks and potential consequences for both the mother and baby, including fetal alcohol spectrum disorders (FASD)[7,8].

While the physical health risks of alcohol and substance use are well-documented, it is equally important to recognize the associated risks of mental health illness. A systematic review revealed that 20-40% of women with an alcohol use disorder also suffered from an anxiety disorder and showed a strong association with major depressive disorder[9,10]. In addition, women who enter treatment for SUD frequently have a personal history of domestic violence, trauma, or sexual assault[11–13]. Domestic violence, trauma, or sexual assault can all have physical consequences, on an individual's physical health which can further impact mental health.

Universal screening for alcohol and substance use in healthcare settings is an effective way to identify individuals in need of help and support but is not widely implemented. Universal screening is defined as providing the same set of questions regarding alcohol and substance use to all individuals, regardless of past medical history or how the patient presents in a healthcare setting[14]. By implementing universal screening for all of their patients, including women of childbearing age (WOCA), healthcare providers minimize the stigma associated with the inquiries. In 2016, implementation of universal screening in primary care practices was less than 3% and less than 1% of the healthcare providers (HCP) subsequently engaged the patient in counseling[15]. Since then, USPTF has recommended universal screening for unhealthy alcohol use for all adults 18 and older within primary care settings, followed by a brief conversation discussing the results[5]. This has resulted in more awareness and use of alcohol and drug screens in private practice settings, but as of 2020, private practice settings have still not met the goals set by the USPTF in 2018[5,16]. USPTF specified the goals of their recommendation were to reduce overall rates of unhealthy alcohol use and improve individual health and social outcomes resulting from risky use through early intervention[17].

Challenges exist for implementing universal screening and supporting WOCA who are at-risk or with alcohol/substance use disorder. For WOCA, one such challenge included a lack of awareness of their risk of misuse as noted in the 2017 Surgeon General's *Facing Addiction Report*[18]. Women who are aware of personal risk may be reluctant to speak with their healthcare professionals out of fear induced by stigma[19,20]. In some states, women are imprisoned for substance use during pregnancy or their children can be taken away[21]. Even if the women had concerns about personal risk and were looking to make an appointment, many were faced with long wait times to receive care [22]. The National Council for Mental Health Wellbeing revealed that 43% of adults were not able to engage in substance use treatment with 28% of those individuals not being able to get an appointment shortly after requesting care[23]. Rural patients may perceive additional barriers related to living in small, close-knit communities where the confidentiality of screener results were perceived as not being as secure as in an urban setting[24–27]. Anonymous self-screening solutions for screening can overcome many of these barriers.

Challenges also exist for Healthcare Providers (HCPs) to implement universal screening and support those at the various stages of risk for alcohol/substance use disorder. One common obstacle is a lack of awareness of recommended screening tools and training on tools and substance use. While 84% of HCPs reported asking young adults about their alcohol use, and 80% of OBGYNs asked about alcohol/substance use as part of a WOCA's visit, the majority of HCPs did not use a validated screening instrument[28] such as the Tobacco, Alcohol, Prescription medication, and Other Substance Use Tool (TAPS-1[29] and the Substance Use Risk Profile–Pregnancy (SURP-P[30]) which are valid and effective in accurately identifying those at risk for substance use[31]. As a result, it is unclear if the risk for alcohol/substance use is being identified in these encounters. In addition, the majority of HCPs are not adequately trained to administer, interpret results, and take appropriate action based on the results of the screeners[25,32]. In addition, providers in rural communities with these skills often have a heavier patient load than urban doctors and as such have less time for a discussion of the screener results, risks, and appropriate next steps [25].

Screening, Brief Intervention, and Referral to Treatment (SBIRT) can be an effective approach in the screening process and referral to treatment for individuals with alcohol/substance use disorder[33]. SBIRT involves Screening for alcohol and substance use for severity, followed by a Brief Intervention (e.g., 10-15 minutes) and, if indicated, Referral to Treatment [33]. SBIRT's effectiveness in reducing alcohol use is well supported across a variety of settings[34]. For example, when SBIRT was implemented in a trauma outpatient clinic, 59% of the patients were identified as being at risk for substance use[33]. SBIRT promotes shared decision-making[35], hinging on clinicians building trust[36], using patient-centered language to reduce stigma[37], and exploring treatment options together. Within primary care settings, SBIRT can help providers identify those suffering from substance use or mental health challenges[38], despite the benefits challenges still exist in implementing SBIRT or other screenings, referrals, and linkage to care in all care settings[39] (e.g. gynecologist offices, etc.) for WOCAs. However, the efficacy of SBIRT's 'brief intervention' portion for drug use in primary care and emergency departments is still under consideration[40] with one systematic review revealing only moderate supporting evidence that interventions in the Emergency Department reduced alcohol-related injuries[41], another showing a reduction in visits to emergency departments following the SBIRT intervention[42], and another study showed mixed evidence surrounding the effectiveness of non-face to face (computerized screening) in the emergency department[43].

The brief intervention offered in SBIRT often incorporates Motivational Interviewing[44]. MI is a collaborative communication style that evokes and seeks to resolve personal ambivalence and strengthen personal commitment and motivation to change the behavior of interest [45]. The 2021 SAMHSA Advisory, *Using Motivational Interviewing in Substance Use Disorder Treatment*, emphasizes the need to discuss each individual's readiness to change and personal history[45]. Engaging clients via the use of MI-Consistent (MICO) skills (e.g., reflections, and affirmations) is a way to evoke personal goals and values consistent with behavior change, thus increasing intrinsic motivation to achieve a healthier lifestyle. However, learning high-quality MI skills can be labor-intensive[46,47], and as such MI is difficult to provide at scale in primary care settings.

Recently, MI has been used in multiple settings and with multiple populations including inpatient, emergency rooms, rural settings[48], and other ethnicities to reduce alcohol/substance use[49–51] and MI via text messages has been well received by adults[52,53]. MI has also been applied through digital format using text messaging to address a variety of health behaviors including tuberculosis[54], smoking[55], and alcohol use[56]. Most recently, chatbots, which are conversational tools that frequently employ artificial intelligence to provide a more engaging approach, have been used in apps (SoberGrid and CHESS) to support motivational interviewing to encourage action towards recovering from substance use[57–59], but as yet no apps exist that

provide screening for SUD and alcohol and related risk factors to encourage change in risky behaviors. The use of electronic screeners (e.g., assessments completed on a tablet) combined with motivational interviewing, can yield more accurate self-reports[60–63].

Digital health technology may be able to address many of these challenges. Smartphone ownership rates are high among women and individuals from diverse backgrounds, with 90% of women and 91-97% of individuals who identify as White, Black, Asian or Hispanic backgrounds having access to a smartphone[64]. Mobile apps are therefore well suited to be used to screen for risk factors in pregnancy[65] and substance use[66] and they can play a crucial role in addressing stigma for those afraid of in-person treatment[67]. With issues related to stigma and fear addressed by the anonymous status, mobile apps can encourage more women to undergo screenings, leading to early identification of at-risk individuals, improved education, and increased treatment options for healthcare providers[68]. Novel digital strategies to improve mental health screenings, patient engagement, and referral to treatment show preliminary effectiveness[69]. A recent report found that using tablets in the waiting room resulted in nearly twice as many individuals screening for depression than when interviewed by nursing staff[70]. Treloar and colleagues highlight that universal screenings can help reduce stigma by reducing discrimination against certain people and groups[71]. As such, mobile health applications have the potential to support universal screening by alleviating stigma, increasing awareness for change through on-demand education, and reducing fear of seeking support and care.

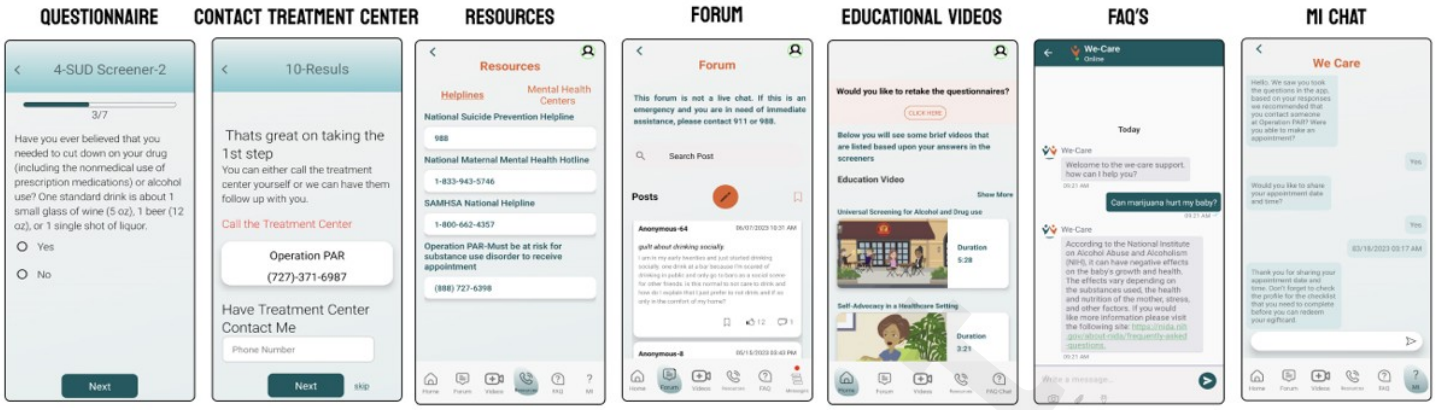
This study was designed to determine whether WOCA will complete anonymous screenings for substance use, alcohol, depression, and anxiety from their mobile phones. We built on prior formative research and online recruitment approaches, explored the benefits of educational and evidence-based materials and the use of linkage to care options, requested feedback on the usability and acceptability of the app, and employed qualitative interviews to determine what future modifications need to be implemented before commercial release.

Methods

Digital Health Tool (DHT) Design

The WE-CARE app was designed to comprise a cross-platform (iOS or Android) mobile app where the participants were asked to complete multiple mental health screeners and then invited to explore each of the accompanying app features. All participants who were assessed as being ‘at-risk’ for either AUD or SUD were advised they could contact a treatment center anonymously or to call the center directly. An initial prototype was tested with 30 participants drawn from the central Florida region, recruited through listservs, a company that provides research participants for a small fee, flyers, and community outreach events. Details of the final design of each of the features to be tested in the pilot are described below.

After extensive formative research[72], the following features were included for pilot testing in the mobile app: E-Screenings for substance use, depression, and anxiety; anonymous self-referral to a local treatment center for further evaluation; a moderated forum for women to ask questions; a list of frequently asked questions to get evidence-based answers; educational videos on substance use and treatment-related information; national and local hotlines for those suffering from anxiety and/or depression; a chatbot to determine whether the women at risk had made an appointment with the partnered treatment center to receive a substance use evaluation; and follow up to the chatbot responses with motivational interviewing via a licensed social worker (**Figure 1**).



Screenshots *of WE-CARE features to be tested in the WE-CARE pilot.*

Screening Instruments.

Multiple screening instruments to be incorporated in WE-CARE were reviewed, and subject matter experts were consulted to determine the most appropriate ones for testing. Four screeners were selected to be used within the app. Immediately after downloading the app, all participants had to take all the screeners: (1) Substance Use Risk Profile-Pregnancy (SURP-P, if the woman self-identified as pregnant); (2) Tobacco, Alcohol, Prescription Medication, and Other Substance Use Tool (TAPS-1); (3) Generalized Anxiety Disorder-2 (GAD-2) for anxiety; and (4) Patient Health Questionnaire-2 (PHQ-2) for depression (**Table 1**). A binary risk assessment (elevated risk or low risk) was immediately provided to the participants who could then store the results within the app or in the phone memory.

Name of the Screener	Description
Substance Use Risk Profile-Pregnancy (SURP-P[73])	A 3-question tool designed for use in prenatal clinics with pregnant women to screen for alcohol, marijuana, illegal substances, and nonprescribed use of prescription medications.
Tobacco, Alcohol, Prescription Medication, and Other Substance Use Tool (TAPS-1[74])	Consists of a combined screening tool that assesses users for commonly used substances, eliminating the need for multiple screening and lengthy assessment tools.
Generalized Anxiety Disorder-2 (GAD-2[75])	A brief questionnaire to determine if someone needs additional screening for generalized anxiety.
Patient Health Questionnaire-2 (PHQ-2[76])	A simple two-question screen to determine if someone should be considered for additional screening for depression.

Screener names and brief descriptions.

If a participant was assessed as having elevated risk for alcohol or substance use, she was offered four choices: (1) she could leave their phone number, but no personal information, so the treatment center could call back within 24-48 hours to provide a standardized intake; (2) she could call a dedicated phone line and reach someone at the treatment center directly; (3) she could call a national or local crisis hotline or (4) she could do nothing. If the woman was NOT at an elevated risk for substance or alcohol misuse but scored high for risk for depression or anxiety, she was presented with a series of crisis hotline numbers to call, as well as contact information for mental health treatment centers in one of the six counties of her choice.

Educational Microlearning Video Production.

Short (1-5 min) animated cartoon videos were produced in Vyond[77] to provide information

identified in the focus groups as pertinent to the women (**Table 2**). Each video topic was researched using websites at NIAAA, NIDA, SAMHSA, and CDC. A script involving two or more characters was then written to provide a more naturalistic setting and conversational tone, and reviewed by subject matter experts for accuracy. A Vyond editor then worked with the producer to provide costumes and a setting tailored to Florida state demographics. To add the personalization desired by the women, the videos were presented in the mobile app based on how an individual answered the screeners, (e.g., if women indicated they were at elevated risk for substance use, videos about the treatment process and general information on substance use were pushed to the top of the playlist).

Several new videos were created for this specific project and additional videos were repurposed from other projects related to breastfeeding for women with SUD (**Table 2**).

Video Topics
What is Universal Screening for Alcohol and Drug Use?
Drug Treatment Center Referral Process
Information for Women about Marijuana Use
Self-Advocacy in a Healthcare Setting
Family Planning
Breastfeeding-How to Pump
Breastfeeding-Opioid Use Disorder
Breastfeeding-Marijuana Use
Breastfeeding-Tobacco Cigarettes
Breastfeeding-Prescription Medications
Breastfeeding-Alcohol Use

Microlearning video topics provided in the WE-CARE app.

Moderated Forum

To ensure the app was providing evidence-based answers, a licensed social worker (LSW) was assigned to the moderated forum. Any participant with access to the app could make a post anonymously, but the forum was ‘moderated’ in the sense that the LSW was scheduled to review posts each morning and would only publish ones that were relevant to the group. The LSW also could post responses to questions in the forum.

FAQs

The most popular FAQ topics and subtopics for women wanting information on substance and alcohol use were identified by querying CHATGPT3[78]. In the formative research stage[72], the women and healthcare providers (HCPs) expressed concern over the credibility of the information in both the moderated forum and the FAQs. As such, answers to the questions were compiled using source materials published at NIH, CDC, and SAMHSA, which were then reviewed by subject matter experts before being published in the FAQ section.

Follow up via a Chatbot and Licensed Social Worker

A chatbot was designed to engage with any individual evaluated as at-risk within 3-4 days of completing the screeners. The chatbot was designed to ask if the person had made an appointment yet and if so, when. After discussion with the chatbot, if an appointment had not been made, a licensed social worker would then engage the participant, in a manner consistent with motivational interviewing, to encourage her to make an appointment with the treatment center for further evaluation.

Additional Resources - National and Local Hotlines and Mental Health Facilities

Links to several national crisis lines were provided in the app such that the participant could

click on the button and be immediately connected to the crisis line through her mobile phone. In addition, for those who self-identified as having either high anxiety or high levels of depression, a list of mental health centers, sorted by county, was provided within the app. All of the mental health centers were confirmed to be taking new patients before including them in the list.

Recruitment

Upon thorough in-house testing of all of these app features, participants were recruited to test the application over a 3-month period. Participants for the pilot study were eligible to participate in the study if they were: 1) women aged 18-44; 2) able to read English at the eighth-grade level; 3) located within Central Florida (one of six counties served by the treatment center); and 4) owned a smartphone device. In addition to recruitment through listservs and contacts in Central Florida, a research assistant posted flyers within the community at healthcare agencies, barber shops, public libraries, and recreation centers. The third approach to recruitment included inviting individuals through Prolific[79], a commercial company that recruits individuals for research projects and surveys.

Demographic information was collected via an online survey instrument embedded in the application and all participants were asked to complete a checklist of the features to test within the app before receiving compensation for participation in the research study. At the end of the app testing, all participants completed an online version of the System Usability Scale (SUS) and several open-ended questions.

Post-Pilot Participant Interviews

Upon completion of the pilot study, participants were recruited via email or through direct messaging using their Prolific IDs to participate in a virtual 1:1 semi-structured interview to gather more feedback on their experience with the mobile app. Interviewers were aware of whether the woman had given the app a low or high SUS score.

Ethical Considerations

The study was approved by the ADVARRA IRB committee (approval no. 00054640). All participants signed electronic informed consent documents before enrollment in the study. Participants were compensated for their time.

Pilot Study Results

Demographics.

Seventy-seven women downloaded the application and a total of 30 women aged 18-44 tested the WE-CARE mobile application. The majority of the participants were white (47%) and not of Hispanic or Latino descent (56.7%). See **Table 3** for a complete description of the ethnic and racial categories of the participants.

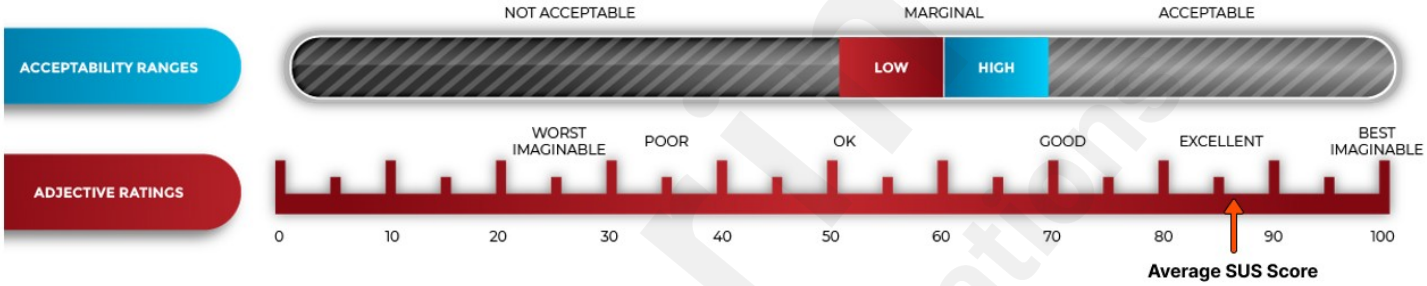
Ethnic Categories	**WOCA from the General Population** (N, % of Total Respondents)
Not Hispanic or Latino	17 (56.7%)
Hispanic or Latino	6 (20%)
Unknown	7 (23%)
Racial Categories	
Black or African American	1 (3.3%)

White	14 (46.7%)
More than one race	5 (16.7%)
Unknown or not reported	7 (23.3%)

Ethnic and racial distribution of study participants.

Usability and Acceptability Score.

WE-CARE was well received by participants who scored it as EXCELLENT (an average SUS score of 86.7 ± 12.43 (SD)). Of the individuals who scored "at-risk" for substance use, the average SUS score was slightly lower, at 84.69 + 12.30 while the individuals who scored "not at risk" for substance use gave the app an average SUS score of 92.73 + 9.14, which would have been considered "BEST IMAGINABLE" (**Figure 2**).



WE-CARE pilot SUS results.

Screening Results

While this was a usability and feasibility study, not a study designed or powered to identify risk for substance use disorders or mental health illness, we did examine the screening results collected in the pilot study. Out of the 30 individuals who completed the screeners, 60% (n=18/30) scored at elevated risk for substance use/alcohol use behaviors, 50% (n=9/18) scored at elevated risk for substance use as well as generalized anxiety, 50% (n=9/18) scored elevated risk for substance use and depression, and 61% (n=11/18) scored at elevated risk for substance use and either high risk for generalized anxiety or depression.

Digital Health Tool Usage Data

Microlearning Video Usage

All of the women had to watch the first video (*Universal Screening for Alcohol and Drug Use*) but reviewing the remaining videos was optional. Using the frequency of views, it is possible to rank the videos in terms of interest, with *Self-Advocacy in the Healthcare Setting* being the second most popular video with six views. As far as the videos were concerned, participants wanted the videos to be less robotic, shorter in length, and to have more videos relating to coping with stress. Participants were asked what additional information they would like to see included in the app, and one participant reported they wanted to learn: *"Strategies and interventions that can be used at home …. (Breathing, mindfulness exercises)"*. Additional suggestions included more information on mental health issues, including *What can I do for fun or to relax instead of drinking or doing drugs? How do I tell if I have an anxiety disorder? What are some ways to reduce anxiety? How do I tell if I have a depressive disorder? What are some ways to alleviate depression?* as well as more information on self-advocacy in the doctor's office.

Moderated Forum Usage.

All participants were required to engage with the forum (e.g. write a post or give a reaction). The forum was pre-seeded with some sample questions and answers, and LIKES were scattered over a variety of posts, indicating the women were reviewing the other posts. One person made an anonymous post to which the licensed social worker then responded.

FAQ Usage.

The women made extensive use of the FAQs, with the majority of the main topics being explored relating to depression, anxiety, or alcohol use in both the main topics and subtopics (**Tables 4-5**).

FAQ Topics	**# of viewings**
General Information About Depression and Anxiety	14
General Facts on Alcohol Use	13
General Information About the Impact of Alcohol and Substance Use on a Child's Health	6
What are Risky Behaviors Related to Alcohol and Drug Use	4
General Information about Family Planning	3
General Information About Fetal Alcohol Spectrum Disorders (FASD)	3
General Information About Domestic Violence	3
General Information about Family Planning	2
General Information About Stigma	2
General Information About Treatments for Alcohol and Substance Use	2
How Does COVID-19 Effect on Drinking Habits, Substance Use, and Mental Health	1

Number of viewings for FAQ main topics.

FAQ Sub-Topics	**# of viewings**
How do you define a standard drink?	7
How to tell if I might have an anxiety disorder?	4
What is considered binge drinking for women?	3
How does drug or alcohol use affect sexual behaviors?	3
How is depression usually displayed in women?	3

What role does stigma (or shame and discredit) play in women receiving treatment for alcohol?	2
What if I did not know I was pregnant and had been drinking heavily on the weekends?	2
What is considered heavy drinking for women?	2

Number of viewings of FAQ sub-topics.

Chatbot and Licensed Social Worker Follow-Up

Although half the individuals scored elevated risk for substance use, none of the women called or left their number with the treatment center or responded when the chatbot reached out to inquire whether they had made an appointment with someone at the treatment center. During the post-pilot focus group discussions, one individual scoring at risk for depression and/or generalized anxiety reported they had reached out to one of the mental health treatment centers within their area.

Qualitative Feedback.

A total of 4 women completed the post-pilot interviews and the demographic information for these participants is provided in **Table 6.**

Ethnic Categories	**WOCA from the General Population** (N, % of Total Respondents)
Not Hispanic or Latino	3 (75%)
Hispanic or Latino	1 (25%)
Racial Categories	
White	2 (50%)
More than one race	2 (50%)

Demographics for post-pilot focus groups.

In addition to providing an objective rating of the app's usability and acceptability using the SUS scoring instrument, we asked several open-ended questions to get qualitative feedback on specific features of the application. In general, the participants were complimentary about the app. One noted, *"I think it's a very simplified app which I actually enjoy. It was a little nostalgic and brought me back to the earlier days of the Internet, especially with the forum included. I did think the screening tests were a little alarming because I wasn't aware I was so depressed. Overall, I enjoyed the app."*

Several participants questioned whether asking just 2 questions on either anxiety or depression was sufficient. One participant commented, *"I think there needs to be additional screening questions. The issues the app wants to tackle require more than the handful of questions asked."* New features suggested by the participants included the ability to add individuals as friends through the app, making the FAQ interactive instead of a list of questions to pick from, and a person-to-person chat option.

When asked whether they had answered honestly when completing the screeners or had been 'playing', all four participants in the post-pilot focus group said they had answered based on their own behaviors. A majority of the participants were not surprised by their scores or alarmed and felt the questions were able to accurately assess their risk for substance/alcohol use, with one participant reporting, *"would have preferred 4-5 questions and would have been good to ask follow up – for instance, in what circumstances are you using (socially, mental coping skills,)…"*. Another

suggestion made by one of the participants involved switching the order of the questions to start with screening for depression and anxiety.

The microlearning videos received more criticism with all participants noting a mix of live-action and cartoon videos would benefit more individuals. The topics of the videos were well received with none of the individuals noting a missed topic. One participant reported, "*topics were really important (esp. drinking a glass of wine*"). A couple of participants felt the length of the videos was sufficient but could be shortened further to 2-3 minutes.

The FAQs did not receive much interaction from the participants, although the participants did feel having the option to look through the FAQ was beneficial to help sort through a lot of information. On the other hand, participants who reported interacting with the moderated forum felt the feature would be helpful with some additional changes such as having a live professional to contact and adding visuals to the page to make the page more "*homey*".

To wrap up the discussion, questions were asked of the participants on how they viewed the motivational interviewing chatbot feature and their overall experience. The participants reported they didn't mind the feature being a chatbot, but if a phone call needed to be made or a person was experiencing an emergency, they believed a human should step in at that point. They also desired the chatbot to provide free follow-up services and to reiterate the individual's information will be kept confidential. Overall, participants felt they would recommend this app to another individual, one person reported, "*Yes … It was marketed to the right population of people; low stakes in terms of divulging deepest darkest truths-allows a space for help that you might need.*"

Discussion

Principal Results

The participants scored the app very highly in terms of usability and acceptability, and enthusiasm was high for the anonymous e-screenings to be offered through a mobile phone application. SAMHSA recommends the use of the SBIRT method to combat the problem of lack of universal screening[80] and this mobile health application successfully provided the screening component of SBIRT. The data collected during the formative research period indicates that WE-CARE can support the SBIRT method by providing universal screening to women from ages 18-44 and educational materials and referrals to partnering treatment centers, but the prototype is not yet capable of replacing the 'brief intervention' component. However, despite providing access to a free licensed counselor at the treatment center, none of the women who participated in this study were ready to seek changes in their behavior as measured by calling the treatment center for further evaluation. One participant did mention in the post-pilot focus group that they did reach out to a mental health facility to address their stress/anxiety, which shows the potential of the app to help women act. The digital handshake, or linkage to care, component of the app, therefore, was not utilized by the participants in the pilot study. After consultation with subject matter experts, it would appear that expecting the women to seek help after completing 5 minutes' worth of screeners on their phone was likely too high a 'bar'. Instead, these results suggest that additional engagement and support would be needed to encourage the women to seek more information or treatment. Plans are underway to redesign the prototype to offer more interactions with both a chatbot and a human counselor to encourage women at risk to engage in the next steps of care.

The educational components of the app (videos, FAQs, and moderated forum) were well received. In the SUS open-ended questions and the post-pilot group interviews, there was significant interest in expanding the educational materials to include additional information on coping skills and mental health (with videos, FAQs, PDFS, etc.). Other recommended additional features included creating a function to invite friends to download the app, adding a person-to-person chat option in

the moderated forum, and making it possible to write in their questions for a chatbot to respond.

Given the women's willingness to complete the screeners on their mobile phones, it does appear it would be advantageous for physicians to implement screening before the appointment or in the waiting room[28,81–83]. Once a screener indicates a woman is at risk for an alcohol or substance use disorder, the next hurdle is for the HCP to offer resources, make proper referrals, or provide suitable treatment options[84]. HCPs require training on how to effectively care for patients with alcohol/substance use disorders and need to understand the underlying reasons why women may engage in such behavior, such as past trauma[85]. Upon review of the screening results, the HCPs could create care plans and provide accessible mental/ behavioral resources to patients based on their specific needs or refer their patients to a current list of clinics accepting new patients. If the latter option, HCPs then need to share with the patient what her journey with a care plan will look like. However, medical school training delivers minimal education in the area of substance use diagnosis and treatment[32] and HCPs have repeatedly noted they feel unprepared to offer SUD treatment or counseling[25,32]. Non-physician or alternate healthcare models may be viable approaches to screening[86] and treatment and digital health technologies such as WE-CARE can help to fill in the time and knowledge gaps in the healthcare workforce.

In this study, over half of the women who completed the screeners in the WE-CARE app scored 'at-risk' for SUD or AUD and rates for risk for depression and anxiety in the respondents were 50% for each. The average rate for women of childbearing age meeting the DSM-IV criteria of SUD or being in treatment in the past year for a SUD in the US is 3.0% for illicit drug use, 1.1% for opioid use, and 7.4% for alcohol use[87]. Similarly, in a study using the same screeners employed in WE-CARE (namely the PHQ-2 for depression and the GAD-2 for anxiety), rates of depression in WOCA have been reported to vary from 10% to 27% in the United States (depending on geographical location, race, and ethnicity[88,89]) and to fluctuate based on COVID prevalence[90]. The rates for anxiety in adults over 18 years of age are equally variable, peaking in 2021 at the height of the COVID pandemic, at 35%[91] but before the pandemic, typically averaging around 19%[92]. Rates for anxiety and depression would be expected to be significantly higher in WOCA than in the general population but gender was not reported in this study[92].

The screeners in WE-CARE were selected to identify women who are at risk for mental illness, not to identify substance use or mental health disorders using the criteria of a DSM-IV diagnosis per se. But there is a chance these rates may not be inflated. This pilot study was completed in a community that had recently experienced a major hurricane that severely impacted the citizens in six counties just 9 months before the study. Increased rates of alcohol and drug use[93] as well as mental illness are not uncommon after natural disasters[94]. Finally, individuals completing the WE-CARE screeners were assured of complete anonymity and therefore the screener results were not verified by individual in-person assessments. When an individual completes an assessment to report risky behavior, it has been demonstrated that the use of assessments completed on a tablet can yield more accurate self-reports[60–63]. However, self-reporting of alcohol or drug use, or concerns with mental illness, may differ in accuracy compared to when a screener is completed in front of a medical professional. The respondent may be confused about the question wording or definitions of terms, or because it was a research study, they may not have given accurate responses. Given the excellent score for usability and acceptability of the app, plans are ongoing to conduct clinical trials where the anonymous screener results will be compared to results from screeners administered by medical professionals to confirm the validity of this approach.

Mobile health 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 the barriers associated with HCP time, stigma, willingness, or ability[95] and therefore are well-suited to the

mobile health application environment. Other tailored apps exist to assist HCPs in delivering health interventions[96–103] related to substance use[96,104–106] and mental health[97,99,102] that are feasible and acceptable, but more research must be conducted to determine if the screeners are valid when delivered via a mobile health app, and also to ensure that after screening, the woman receives sufficient guidance and support to seek treatment if needed[107,108].

Limitations

A key limitation of this study was the self-selection recruitment method employed, which may have impacted the generalizability of the findings. Future studies will include samples from a larger, more diverse population. Moreover, it is possible that only women who had concerns about their mental health opted to participate in the research study. Also, as discussed above, responses generated through self-report may be flawed if the respondent misunderstands the questions or doesn't answer truthfully. Future versions of this tool will be tested in general clinics, where all patients will be asked to download the app as part of their annual physical and to talk with their healthcare provider after completing the screeners.

Conclusions

Preliminary results on the usability and feasibility of the WE-CARE mobile health app in providing anonymous screenings for drug and alcohol use, as well as anxiety and depression, are excellent. Participants readily completed the screeners and were enthused about the opportunity to learn more about a variety of topics tailored for women in their childbearing years. Further research is necessary to validate this approach and to determine how to encourage women who score at risk for significant substance use and/or mental illness to seek treatment.

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Conflicts of Interest

TXM and HKC are co-owners of Benten Technologies, the company designing this platform, and will eventually market the WE-CARE mobile app. The remaining authors declare that the research was conducted without any commercial or financial relationships that could be construed as a potential conflict of interest. The content is solely the responsibility of the authors and does not necessarily represent the official views of NIH, the Department of Veterans Affairs, or the United States Government.

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Abbreviations

AUD	Alcohol Use Disorder
CDC	Centers for Disease Control and Prevention
FAQ	Frequently Asked Questions
HCP	Healthcare Providers
GAD-2	Generalized Anxiety Disorder-2
IRB	Institutional Review Board
LSW	Licensed Social Worker
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIDA	National Institute on Drug Abuse

PHQ-2	Patient Health Questionnaire-2
SAMHSA	Substance Abuse and Mental Health Services Administration
SBIRT	Screening, Brief Intervention, and Referral to Treatment
SUD	Substance Use Disorder
SURP-P	Substance Use Risk Profile–Pregnancy
SUS	System Usability Scale
TAPS-1	Tobacco, Alcohol, Prescription medication, and Other Substance Use Tool
USPTF	United States Preventative Task Force
WE-CARE	Women Empowered to Connect with Addiction Resources and Engage in Evidence-based Treatment
WOCA	Women of childbearing age

Supplementary Files

Figures

Screenshots of WE-CARE features to be tested in the WE-CARE pilot.

WE-CARE pilot SUS results.