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Electronic Monitoring Of Mom's Schedule (eMOMS^{TM}): Recruitment of pregnant populations with elevated BMI in a feasibility randomized controlled trial

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ABSTRACT

Underrepresentation of pregnant populations in randomized controlled trials of lifestyle change interventions is concerning due to high attrition and providers' limited clinical time. The purpose of this evaluative study was to assess intervention uptake of pregnant individuals enrolled in a three-arm feasibility randomized controlled trial, electronic Monitoring Of Mom's Schedule (eMOMS^{TM}), examining lifestyle changes and lactation support alone, and in combination. Measures included: (1) participation and completion rates, and characteristics of intervention completers versus other eligible participants; and (2) provider experiences with screening and enrolling pregnant participants. Pregnant people with a pre-pregnancy body mass index $\geq$ 25 and $<$ 35 kg/m^2 were enrolled into the eMOMS^{TM} trial between September 2019 - December 2020. Of the 44 consented participants, 35 were randomized, at a participation rate of 35%, and 26 completed the intervention, resulting in a completion rate of 74%. Intervention completers were slightly older and entered the study earlier in pregnancy compared to non-completers. Completers were more likely to be first-time mothers, resided in urban areas, had higher educational attainment, and were slightly more racially and ethnically diverse. A majority of providers reported willingness to participate, believed the study aligned with their organization's mission, and were satisfied with using iPads for screening. Lessons learned to guide recruitment success include use of: (1) designated research staff in combination with physician support; and (2) user-friendly technology to help mitigate time burden on physicians and their staff. Future work should focus on successful strategies to recruit/retain pregnant populations in clinical trials.

1. Background

Pregnancy is an ideal time to implement lifestyle changes for chronic disease management (Rockliffe et al., 2021).People are more likely to modify their behavior to benefit their unborn child and stay engaged after birth when lifestyle change interventions start during pregnancy (Rockliffe et al., 2021; Gillman and Ludwig, 2013).However, recruitment of pregnant individuals into clinical trials is challenging and exclusion of this population remains common practice (Bagherzadeh et al., 2021; Ayyala et al., 2020; Seward et al., 2018). This is mainly due to individuals' perception of potential harm to the fetus, no benefit to the pregnant person, feelings of uncertainty, time constraints, and beliefs of adverse pregnancy outcomes (Frew et al., 2014; Oude Rengerink et al., 2015). Other critical barriers sustaining the underrepresentation

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of pregnant populations include liability fears, study design calling for specific inclusion/exclusion criteria, federal guidelines for human subjects protection, and historical tragedies such as the use of thalidomide and diethylstilbestrol (i.e., DES) during pregnancy and their devastating impact on the developing fetus (Van der Zande et al., 2018).

Studies of people with overweight or obesity can be particularly complicated due to high attrition, with psychological (e.g., body dissatisfaction, poor body image, low self-efficacy, low social support, poor mental health) and behavioral (e.g., low levels of physical activity, more past dieting attempts, financial difficulties) variables being the most predictive of intervention dropout rates (Moroshko et al., 2011). Moreover, limited clinical time in patient care keep providers from informing pregnant people about study participation (Daly et al., 2019; Rose et al., 2021; Williams et al., 2020).

To date, there is an increasing interest in studying successful strategies and best practices to recruit pregnant individuals. Active recruitment, described as strategies using direct or person-to-person interactions between study staff and potential participants, appears to yield higher recruitment rates compared to passive recruitment, described as strategies using flyers/brochures, targeted postcard mailings, electronic mail listservs and no direct or person-to-person interactions with potential participants (Goff et al., 2016; Sutton et al., 2017; Estabrooks et al., 2017). As a best practice, Frew et al. argued for a combination of prenatal care provider involvement and engagement of community-based organizations to successfully recruit and retain pregnant people (Frew et al., 2014). Goldstein et al., reported that building trusting relationships and employing diverse recruitment methods facilitated recruitment of pregnant populations whereas a lack of cultural sensitivity formed a barrier (Goldstein et al., 2021). Further, Goff et al. reported success in using strategies grounded in a health equity framework to recruit and retain racially and ethnically diverse pregnant populations (Goff et al., 2016).

In summary, these studies suggest that use of multiple recruitment methods involving healthcare providers, clinical staff, and community partners play a critical role in the screening and recruitment of pregnant populations. Despite these findings, pregnant populations are still largely underrepresented in clinical trials of lifestyle change interventions (Blehar et al., 2013). For the present study, we assessed uptake of a lifestyle change intervention at the participant and provider levels of pregnant individuals enrolled in a feasibility randomized controlled trial examining lifestyle changes and lactation support alone, and in combination. Measures included: (1) participation and completion rates, and characteristics of intervention completers versus other eligible participants; and (2) provider experiences with screening and enrolling pregnant participants.

2. Methods

For our evaluation, we assessed two dimensions: reach at the participant level and adoption at the provider level, as described in the RE-AIM theoretical framework (Glasgow et al., 1999; Glasgow et al., 2019;). We described reach as the participation rate (computed as the proportion of those screened who participated), the completion rate (computed as the proportion of enrolled randomized participants who completed at least 80% of the intervention), and we compared characteristics across completers and all other eligible participants. We described adoption as provider (i.e., physician and staff) experiences toward participant recruitment. The study was approved by the Institutional Review Board of Ascension Via Christi Hospitals Wichita, Inc., relied on by the University of Kansas School of Medicine-Wichita Institutional Review Board.

Detailed information regarding study design and methodology for the eMOMS^{TM} feasibility randomized controlled trial is described elsewhere (Jacobson et al., 2020). In brief, the three-arm trial included an online 12-month intervention developed by our team and modelled after the national Diabetes Prevention Program (DPP) that was offered alone or in combination with lactation support, versus a health coaching control condition. Study eligibility criteria were intended to obtain a study population with a low likelihood of developing pregnancy complications and included those who were aged 18 older, $\leq$16 weeks gestation at study entry, and with pre-pregnancy body mass index of $\geq$ 25 and $<$ 35 kg/m^2 (Jacobson et al., 2020).

Study Purpose 1: Examine Participation and Completion Rates and Compare Characteristics of Intervention Completers versus Other Eligible Participants.

To accomplish this purpose, we described the recruitment and study flow of participants and compared socio-demographic characteristics among intervention completers, defined as enrolled randomized participants who completed at least 80% of the intervention, versus other eligible participants, defined as those who consented to participate in the study but did not complete the intervention. Study participants were recruited for the eMOMS^{TM} study (registered at Clinical.Trials.gov with identifier: NCT04021602) from two sites: one rural obstetrical clinic and one urban obstetrical clinic, both located in a Great Plains rural state. Participants were recruited between September 2019 and December 2020. Pregnant individuals with BMI $\geq$ 25 and $<$ 35 kg/m^2 and who met eligibility criteria were recruited into the study by 1) prescreening and on-site screening by clinic personnel at each study site; 2) screening by study coordinator at the urban site only; and 3) self-referral.

Prior to study commencement, the principal investigator (PI) and her research coordinator trained providers and their staff on the use of an iPad, talking points, and engagement touchpoints. Two weeks prior to their prenatal appointment, clinic staff would prescreen pregnant women, flag those who met eligibility criteria, and notify the research coordinator of appointment days/times. During this appointment, the physician would familiarize a potential participant with the study's purpose, and, if interested, would then refer her to the coordinator, who was readily available onsite (or via video platform for the rural site). If all criteria were met, then the coordinator would obtain informed consent, provide study-related information, and schedule a virtual 30-minute orientation session.

Interactive one-page flyers and tri-fold study brochures were also developed and posted in the waiting and exam rooms of each study site. Each contained a website link named "Do I qualify for eMOMS?" that individuals could go to and answer eligibility questions. These study materials were also posted on social media by key community partners who collaborated with the PI on this study.

Study Purpose 2: Examine Provider Experiences with Screening and Enrolling Pregnant Participants.

To accomplish this purpose, we developed a survey instrument that contained closed-ended questions measuring the following constructs: (1) willingness to participate in the eMOMS^{TM} study (three questions); (2) perspectives on screening pregnant individuals (six questions); (3) perspectives on enrolling pregnant individuals (seven questions); (4) beliefs and attitudes toward study implementation (seven questions); and (5) barriers and facilitators to study participation (four questions). Data on gender, race/ethnicity, position, location, and setting were obtained as well (six questions). Item responses to each of the questions included Likert-type scale response anchors (i.e., very easy, easy, neutral, difficult, very difficult; or, extremely satisfied, very satisfied, moderately satisfied, slightly satisfied, not at all satisfied), multiple choice, and dichotomous (i.e., yes/no) responses. The survey instrument was piloted among five medical staff members not affiliated with the study. Their feedback to simplify wording and shorten the length of several questions was incorporated into the survey's final version.

Upon completion of the eMOMS^{TM} trial, the survey instrument was distributed via electronic mail (e-mail) to a total of 26 healthcare providers and staff members, of which 17 were located in a rural area and nine in a metropolitan area. Data were collected between June and August 2021. Consent was obtained prior to starting the survey and participation was voluntary and anonymous. Participants were provided

the option to enter a drawing for a $20 gift card. The survey took approximately 10–15 minutes to complete.

2.1. Data management and analysis

Data were collected using Research Electronic Data Capture (REDCap), a secure web-based application designed to support data capture for research studies hosted at the University of Kansas School of Medicine–Wichita (Harris et al., 2009). When comparing characteristics between intervention completers versus all other eligible participants, means were compared with independent samples t-tests and categorical data were compared with Fisher's exact test. Descriptive statistics are presented on all identified constructs and sociodemographic characteristics. Only completed surveys were used for analysis.

3. Results

Study Purpose 1: Examine Participation and Completion Rates and Compare Characteristics of Intervention Completers versus Other Eligible Participants.

Of the 100 individuals screened, 80 and 18 were screened by urban and rural healthcare providers respectively; two individuals screened themselves through the website. After meeting eligibility criteria (see Table 1), 44 individuals consented to participate, of which nine did not complete baseline questionnaires. Upon survey completion, 35 were randomized resulting in a 35% participation rate (35 of the 100 screened) and 26 completed the intervention, resulting in an intervention completion rate of 74% (see Fig. 1).

Table 2 summarizes characteristics of intervention completers (N = 26) versus all other eligible participants (or non-completers) (N = 18). Completers were slightly older 27.7 ± 5.5 years versus 26.9 ± 6.7 years. Completers entered the study slightly earlier in pregnancy at 12.6 ± 2.4 gestational age versus non-completers at 14.2 ± 2.4. Compared to non-completers, completers were also more likely to be first-time mothers (50% vs. 11%), with a higher incidence of diabetes (8% vs. None). Additionally, 71% of completers held private or employer provided insurance compared to 56% of non-completers. Intervention completers were also more likely to hold higher educational degrees. Income levels across both groups were represented somewhat equally and completers were slightly more racially and ethnically diverse, with the majority identifying as non-Hispanic White, followed by Hispanic and non-Hispanic Black. Last, completers had an increase in breastfeeding knowledge that was sustained through six-months postpartum.

Table 1
Eligibility Criteria.

Inclusion
1. Pregnant
2. ≤ 16 weeks gestation at recruitment
3. BMI ≥ 25 and < 35 kg/m^2
4. At least 18 years old or older
5. Interested in breastfeeding
6. Have a cell phone and internet access
7. Able to understand English
8. Able to use Facebook
9. Able to use a video platform
Exclusion
1. BMI ≥ 35 kg/m^2
2. Current smoker
3. Multiple gestation
4. Substance abuse within last 3 years
5. In weight-loss program 3 months prior to pregnancy
6. IVF (In-Vitro Fertilization) pregnancy
7. Diagnosed with or treated for thyroid disease
8. Diagnosed with life-threatening pregnancy complications as determined by healthcare provider
9. Prior bariatric surgery
10. Pregnancy complicated with a fetus diagnosed with lethal malformation/condition
11. Unwilling to participate in study procedures
12. Presence of any condition that limits walking
13. Presence of any condition that limits diet suggestions

Study Purpose 2: Examine Provider Experiences with Screening and Enrolling Pregnant Participants.

Eight out of 26 providers and staff completed the survey, for a response rate of 31%. The majority of respondents (83%) identified as female, 33% self-identified as Hispanic, and 67% reported working within an urban setting (see Table 3). All respondents were willing or very willing to participate in the program. All participants noted that the program was either an excellent or very good fit for the mission and purpose of their organization. The majority of respondents (86%) reported that training on how to screen pregnant women was excellent/very good and expressed confidence (83%) in telling pregnant women about the program. Eighty percent of respondents reported that they were confident in screening and enrolling pregnant women into the program, using an iPad. Last, the most reported (75%) challenge was not having a designated paid person to screen and enroll eligible participants.

4. Discussion

This study assessed the feasibility of screening and enrolling pregnant individuals with BMI ≥ 25 and < 35 kg/m^2 into a randomized controlled trial. Identifying factors that affect the ability to recruit this population along with characteristics that may impact study participation will work to improve recruitment strategies for future studies. The eMOMS^{TM} trial (Jacobson et al., 2020) was a novel approach to assist pregnant individuals with implementing a healthy lifestyle. Our flow diagram and comparison of intervention completers versus non-completers provide a valuable assessment of study participation and completion at the participant level. At the provider level, experiences related to participant recruitment serve as a proxy for feasibility of study adoption within healthcare systems.

Study Purpose 1: Examine Participation and Completion Rates and Compare Characteristics of Intervention Completers versus Other Eligible Participants.

This study reports several key findings: (1) an acceptable intervention completion rate; (2) characteristics associated with intervention completers versus non-completers were similar; and (3) intervention non-completers demonstrated increased breastfeeding knowledge at baseline. Each of these findings is discussed below.

We demonstrated a high completion rate among consented participants (74%), just short of our goal of 80% (Jacobson et al., 2020). This is consistent with previous feasibility studies related to health interventions in early pregnancy (Bailey et al., 2020; Huang et al., 2020; Hughes et al., 2018).Weight-related interventions continuing *into* or initiated *during* the postpartum period have not yet demonstrated retention rates > 80%, largely due to the time demand and other challenges women experience in this transitional life stage (Vincze et al., 2019).

It is possible that the substantial time commitment of our 12-month intervention may have deterred women from participating. Nine of the 44 consented participants did not complete survey instruments, so they were never randomized. Also, following randomization, another nine participants withdrew during the first couple of weeks without indicating a reason (except for two who experienced a non-study related serious adverse event and decided not to continue with the intervention). As most withdrawals occurred early in the intervention, women may have started to realize the time burden once they consented and consequently dropped out. Studies report that efforts to reduce time burden for participants include reducing the need for a participant to contact the study team on their own, periodic data checks to assess study completion, maximizing downtime during clinic visits, and completion of fewer questionnaires (Goff et al., 2016). Moving forward with a large-scale efficacy trial, we will consider employing some or all of these

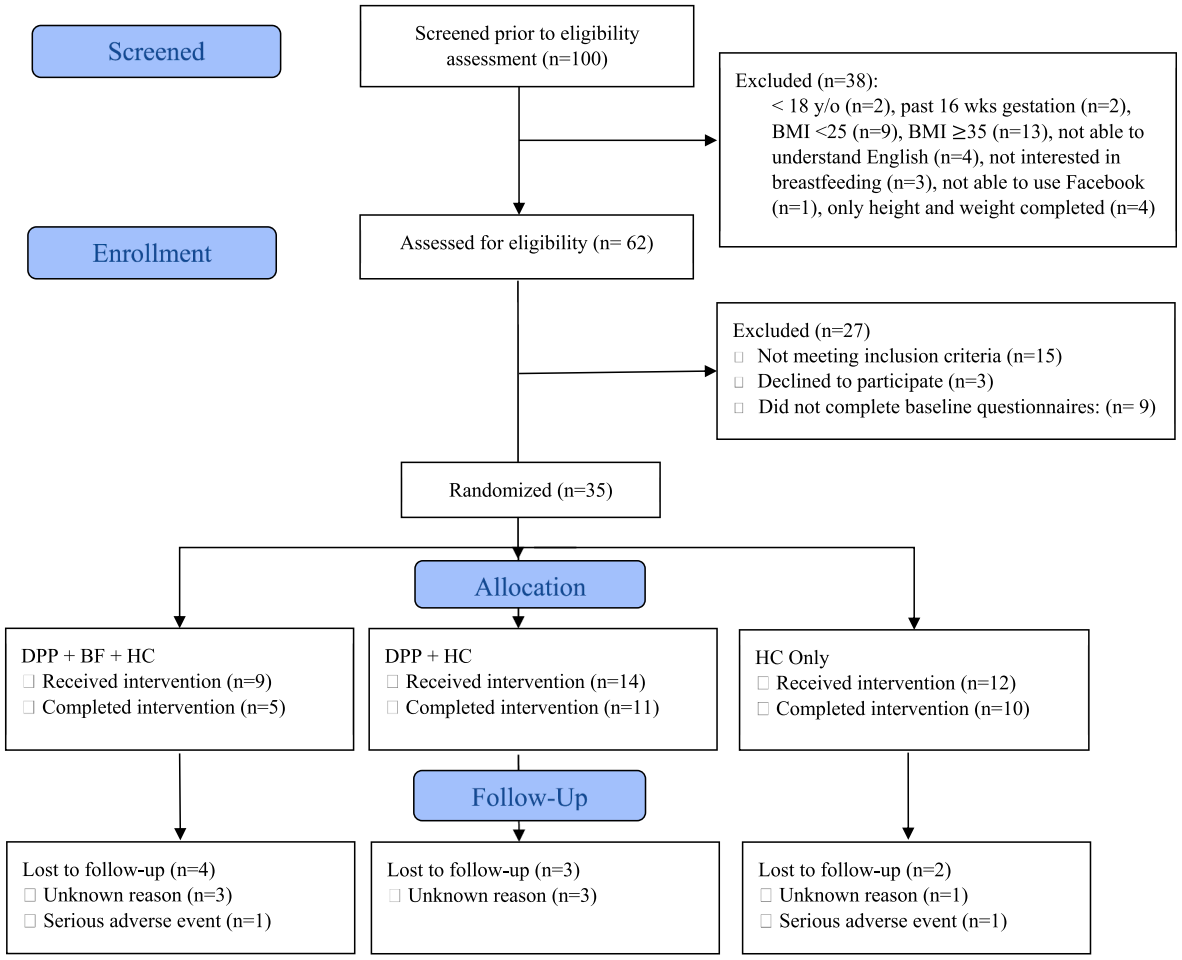

Fig. 1. CONSORT 2010 Flow Diagram of eMOMS Feasibility Study. DPP = Diabetes Prevention Program BF = Breastfeeding HC = Health Coaching.

techniques.

In our study, those who completed the intervention were similar to those classified as non-completers in BMI, age, and income. Participants who completed the intervention were likely representative of our target population. Intervention completers were slightly more diverse than the Kansas population (%) [69% (86%) non-Hispanic White, 12% (6%) non-Hispanic Black, and 15% (12.7%) Hispanic] (U.S. Census Bureau QuickFacts: Kansas. www.census.gov. https://www.census.gov/quickfacts/KS. Accessed November 3, 2022). Also, at study entry, intervention completers were slightly earlier in their pregnancies, compared to non-completers. Liu et al. also noted this trend in their analysis of recruiting pregnant individuals with elevated BMI (Mean Gestational Age: 10.1 vs 10.6, p = 0.03) (Liu et al., 2020). Early pregnancy appears to be an ideal time to start implementing lifestyle changes though it is unclear to what degree earlier gestation correlates to higher rates of study completion and further research in this area is needed.

Additionally, completers in our study were more likely to reside in an urban location, compared to non-completers. Increased participation from urban participants was in part due to better, more consistent recruitment practices at the urban site as a study team member was on-site and actively recruited participants. We understand that recruiting rural participants into research studies has specific limitations including distance from study site (Bonevski et al., 2014). Regardless from geographic location, our study's recruitment was also negatively affected by the COVID-19 pandemic as focus of healthcare providers shifted to managing an emergent public health crisis.

Last, all income levels were represented in both groups, though the majority reported a household income less than $50,000. This is notably less than the median household income in the state of Kansas ($61,091) (U.S. Census Bureau QuickFacts: Kansas. www.census.gov. https://www.census.gov/quickfacts/KS. Accessed November 3, 2022). It is difficult to determine if income played a role in recruitment and retention of our study participants. Individuals of lower socioeconomic status may be more likely to find value in a lifestyle intervention particularly if they have less social support and resources during pregnancy. On the other hand, those with less social support are also more likely to study drop-out (Moroshko et al., 2011). Further, these populations are more likely to have elevated BMI and therefore meet study eligibility criteria (Ogden et al., 2017). Additional examination of the roles that socioeconomic status and study eligibility criteria play in relation to participant recruitment/retention is warranted.

Finally, the higher self-reported breastfeeding self-efficacy score in non-completers at study entry may have contributed to drop-out among consented participants and lack of participation by other eligible participants. Likewise, prior bias and experience with breastfeeding likely contributed to perceived value of the intervention. This may be especially true in multiparous women who were more likely to be in the non-completer group as compared to the higher proportion of completers being primiparous. Perceived usefulness and personal gain are key motivators among individuals participating in lifestyle interventions (Kozica et al., 2015) and is the primary indicator of acceptance of virtual lactation support interventions (Chua et al., 2022). Improvement in breastfeeding knowledge seen with a combination of online support, breastfeeding resources, and one-on-one health coaching is consistent with previous studies that have conducted similar multi-faceted interventions (Chua et al., 2022).

Table 2
Characteristics of Completers and All Other Eligible Participants.

		Completers	All Other Eligible Participants*	
		Yes=26	No=18	
Description	**N**	**n (%)**	**n (%)**	**p**
Location	44			0.128
Urban		23 (88)	12 (67)	
Rural		3 (12)	6 (33)	
Mean age (SD)	35	27.7 (5.5)	26.9 (6.7)	0.722
Mean BMI (SD)	39	29.6 (2.8)	30 (3.5)	0.613
Mean Gestational Weeks Age (SD)	35	12.6 (2.4)	14.2 (2.4)	0.094
Race /Ethnicity	35			0.439
White, non-Hispanic		18 (69)	5 (56)	
Black, non-Hispanic		3 (12)	1 (11)	
Hispanic/Latina		4 (15)	1 (11)	
Other		1 (4)	2 (22)	
Income	35			0.899
$9,999 or less		7 (27)	2 (22)	
$10,000 to $24,999		3 (12)	1 (11)	
$25,000 to $49,999		7 (27)	2 (22)	
$50,000 to $74,999		3 (12)	2 (22)	
$75,000 to $99,999		5 (19)	1 (11)	
$100,000 or more		1 (4)	1 (11)	
Highest Level of Education	35			0.586
Some high school		1 (4)	2 (22)	
Graduated from high school		5 (19)	1 (11)	
Some college		8 (31)	2 (22)	
Graduated with an associate degree		3 (12)	2 (22)	
Graduated with a bachelor's degree		8 (31)	2 (22)	
Advanced degree (e.g., Masters, PhD, MD, JD)		1 (4)	0 (0)	
Insurance Status	35			0.416
Private (Employer Provided)		19 (71)	5 (56)	
Public (Medicaid, KanCare)		7 (27)	4 (44)	
WIC Recipient	7	5 (19)	2 (22)	>0.999
Trimester	35			>0.999
First		16 (62)	5 (56)	
Second		10 (39)	4 (44)	
Total Number of Pregnancies, Not including current	35			0.027
None		13 (50)	1 (11)	
1 birth		5 (19)	3 (33)	
2 births		2 (7)	4 (44)	
3+ births		6 (23)	1 (11)	
Diabetes, Prior to Pregnancy	2	2 (8)	0 (0)	
Gestational Hypertension	5	3 (12)	2 (13)	
BSES-SF: Prenatal (SD)	35	37.5 (14.3)	52.1 (12.0)	0.010
BSES-SF: 6 Month Postnatal (SD)	28	48.7 (19.3)	28.5 (16.3)	0.163

Notes BSES-SF = Breastfeeding Self-Efficacy Scale-Short Form.
SD = Standard Deviation.
* = Refers to those who consented but did not complete intervention.

Study Purpose 2: Examine Provider Experiences with Screening and Enrolling Pregnant Participants.

A recent pilot intervention for pregnant women with diabetes saw an unprecedented adherence rate of 93%, along with successful recruitment; authors noted that study sites had a strong, pre-established commitment to diabetes prevention that may have contributed to the program's success (Carter et al., 2022). More importantly, they concluded that buy-in of study site providers and staff were key drivers to successful recruitment outcomes. Our key findings related to assessment of providers' experiences appear consistent with these authors' reported results: (1) a strong willingness to participate; (2) confidence in

Table 3
Summary of Provider Responses.

Questionnaire / Response	Total N	Respondents n	Respondents %
Demographics			
What is your gender? / Female.	6	5	83.3
What is your race? / White.	6	6	100.0
What is your ethnicity?	6		
Non-Hispanic		4	66.7
Hispanic or Latino		2	33.3
Is your workplace in a rural or urban setting?	6		
Rural		2	33.3
Urban		4	66.7
Questionnaire			
Where did you talk to pregnant women about the eMOMS program? / In a clinic exam room.	4	3	75.0
How willing were you to participate in the eMOMS program?	8		
Very Willing		6	75.0
Willing		2	25.0
Has your willingness to participate in the eMOMS program changed over time? / No.	8	7	87.5
How well does the eMOMS program fit the mission and purpose of your organization?	8		
Excellent fit		2	25.0
Very good fit		6	75.0
How satisfied were you with using an iPad to screen participants? / Very satisfied.	5	4	80.0
Prior to implementation of the eMOMS program, what did you think of the training on how to screen pregnant women?	7		
Instruction was excellent		3	42.9
Instruction was very good		3	42.9
Would you have liked to receive additional training on screening pregnant women? / No.	7	7	100.0
Did you face any challenges in identifying pregnant women to participate in the eMOMS program? / No.	7	7	100.0
How often did you screen pregnant women for the eMOMS program?	7		
More than once a week		2	28.6
I did not screen pregnant women		3	42.9
How many pregnant women in totality did you screen for the eMOMS program?	7		
I did not screen any women		3	42.9
I do not know		2	28.6
What percentage of screened women did you enroll into eMOMS?	6		
1-10%		3	50.0
I did not enroll any screened participants		2	33.3
How confident were you in screening pregnant women into the eMOMS program? / Confident.	5	4	80.0
How confident were you in enrolling pregnant women into the eMOMS program? / Confident.	5	4	80.0
Would you have liked to receive additional training on how to enroll pregnant women into the eMOMS program? / No.	6	6	100.0
How confident were you in telling eligible pregnant women about the eMOMS program?	6		
Very confident		2	33.3
Confident		3	50.0
Did you face any challenges in enrolling pregnant women into the eMOMS program? / No.	5	4	80.0
How many women in totality did you enroll into the eMOMS program?	6		
1 to 5		2	33.3
I did not enroll any women		2	33.3
How difficult was it to incorporate the eMOMS program into your job?	5		
Easy		2	40.0
Neutral		3	60.0
How often did you use the eMOMS study brochures when talking to pregnant women?	5		
Almost every time		3	60.0
Sometimes/Occasionally		2	40.0
Do you think that the role of healthcare providers and/or clinical staff in the eMOMS program should be changed? / I do not know.	5	4	80.0

(*continued on next page*)

Table 3 (*continued*)

Questionnaire / Response	Total N	Respondents n	%
How satisfied are you with the content of the eMOMS program? / Very satisfied.	4	3	75.0
Was there anything in the eMOMS program you would have liked to see more of, less of, or was the program content just enough? / eMOMS program content was just enough	4	4	100.0
What evidence-based information would you like to see added to the eMOMS program? Check all that apply.	6		
Postpartum maternal psychological well-being		2	33.3
Nothing, I like the program the way it is		3	50.0
Did the eMOMS certified lifestyle coach interfere with your clinical relationship with the patient?	5		
No		3	60.0
Does not apply		2	40.0
What do you think is a major STRENGTH of the eMOMS program? Check all that apply.	6		
Focus on mom's health		3	50.0
Ongoing support after baby arrives		2	33.3
What do you think is a major WEAKNESS of the eMOMS program? / Online program delivery using Facebook.	2	2	100.0
What challenges exist for healthcare workers to be involved in the eMOMS program? Check all that apply.	4		
Learning about the content of a new program		2	50.0
Learning about eligibility criteria to enter the program		2	50.0
Not having a designated person who is paid to screen and enroll eligible women		3	75.0

talking to eligible individuals about the intervention; and (3) high satisfaction with the process of screening and recruitment.

Most respondents found the study to fit their mission and purpose, which may have contributed to their willingness to participate in the study and follow-up survey. The use of technology such as an iPad may have contributed to a positive experience as well. Willingness to participate and study alignment to organizational mission are important indicators of study feasibility as they enhance study uptake particularly in research-hesitant settings. Brooks et al. demonstrated that rural providers may be more likely to be involved in research that addresses pertinent problems (e.g., obesity) in their community and is highly relevant to their patient population (Brooks et al., 2020). Our findings of high confidence and satisfaction with recruitment are also factors that contribute to recruitment success (Rose et al., 2021).

One of the challenges to research involvement was not having a paid person to screen and enroll eligible participants. This could relate to the additional time burden placed on providers and healthcare staff. For pregnant populations, evidence suggests that active recruitment, described as using direct person-to-person interactions between study staff and potential participant, by a compensated member of the study team may be the ideal mode of recruitment resulting in the highest yield (Rose et al., 2021; Goff et al., 2016; Sutton et al., 2017; Liu et al., 2020). Nonetheless, these types of studies are extremely expensive and this is also not to say that the obstetrics provider does not have a key role in recruitment and retention. Patients appear more likely to enroll in studies that their provider supports and is knowledgeable about (Goff et al., 2016; Sutton et al., 2017; Liu et al., 2020; Ross et al., 1999). Other passive methods, described as using brochures, flyers, social media advertisements and no direct person-to-person interactions with potential participants, reach a smaller portion of eligible participants but appear to be more cost efficient (Estabrooks et al., 2017). One of the objectives of this case study was to test the feasibility of the use of providers to screen and enroll potential participants and so we cannot conclude with any degree of certainty that use of a paid staff member to screen and enroll participants works. Additional research into the cost and use of paid research staff related to screening and enrolling participants is needed.

4.1. Limitations

Rural-urban differences pertaining to recruitment of pregnant populations cannot be fully assessed due to small sample size. Additionally, interpretation of provider survey results is limited due to a low response rate and potential recall bias as the survey was completed 12 months after participant recruitment. Provider experiences with screening and enrolling pregnant individuals may not represent that of all providers and healthcare staff who were involved with the study. Last, our recruitment window occurred during the onset of the COVID-19 pandemic, which likely impacted study participation and outcomes as providers and healthcare staff were focused on managing a developing public health crisis.

5. Conclusion and implications for future research

Recruitment for our feasibility study was adequate with retention similar to other lifestyle interventions during pregnancy. Contributors to recruitment and retention include time burden for participants, site-specific recruitment strategies, pregnancy gestation at time of enrollment, socioeconomic factors, and perceived value of the intervention. Lessons learned that will guide recruitment success of a multisite, large-scale randomized controlled trial include: (1) using designated research staff to actively recruit participants in combination with provider support as the primary means of study recruitment; (2) passive strategies (i.e., social media ads) can also be used to maximize reach and recruitment yield; (3) high perceived value and convenience are essential in an individual's decision to participate in a study, and (4) user-friendly technology can improve experience, adherence, and access for both the personnel involved in study recruitment and individual study participants. Future studies are needed to further describe factors that influence recruitment and retention of pregnant populations to lifestyle interventions.

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7. Clinical trial identifier

NCT04021602.

8. Trial registry name/study title

Diabetes Prevention Program Feasibility Study of Breastfeeding.

9. Human subjects approval statement

The study was approved by the Institutional Review Board of Ascension Via Christi Hospitals Wichita, Inc., relied on by the University of Kansas School of Medicine-Wichita Institutional Review Board. All participants provided informed consent prior to initiation of the study.

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CRediT authorship contribution statement

Lisette T. Jacobson: Conceptualization, Methodology, Investigation, Writing – original draft, Supervision, Project administration, Funding acquisition. **Michael Wolfe:** Conceptualization, Resources, Writing – original draft. **Rosey Zackula:** Formal analysis, Data curation, Writing – original draft. **Hayrettin Okut:** Methodology, Formal analysis, Writing – original draft. **Faith E. Hampton:** Resources, Writing – original draft. **David A. Grainger:** Conceptualization, Resources, Writing – review & editing. **Adrianne K. Griebel-Thompson:** Resources, Writing – original draft, Writing – review & editing. **Kai Ling Kong:** Conceptualization, Writing – review & editing. **Christie Befort:** Conceptualization, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

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