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Recruitment challenges and enrollment observations from a community based intervention (*Mothers In Motion*) for low-income overweight and obese women

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ABSTRACT

Background: *Mothers In Motion (MIM),* a randomized controlled trial, aimed to help young, low-income overweight and obese mothers prevent weight gain by promoting stress management, healthy eating, and physical activity. This paper describes *MIM* recruitment challenges and reports demographic characteristics affecting enrollment.

Methods: Participants who were African American or Non-Hispanic White were recruited from the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) in Michigan. We faced numerous recruitment challenges and learned that several strategies facilitated recruitment. Logistic regression analyses were performed to examine demographic characteristics that affect enrollment.

Results: Women who had a higher body mass index (BMI, OR 1.06, 95% CI 1.02–1.10); were at late postpartum, (OR 1.24, 95% CI 1.10–1.40), were breastfeeding (OR 5.0, 95% CI 2.34–10.65); or were at early postpartum and breastfeeding (OR 0.42, 95% CI 0.22–0.81) were more likely to enroll than their counterparts. Compared to African American women, Non-Hispanic White women were more likely to enroll (OR 1.77, 95% CI 1.29–2.42). Also, women who were non-smokers (OR 0.54, 95% CI 0.40–0.73) or had a higher education were more likely to enroll (OR 1.21, 95% CI 1.04–1.42) than those who smoked or had a lower education.

Conclusion: Future lifestyle behavioral intervention studies for similar target audiences may consider tailoring their recruitment messages based on relevant participant demographic characteristics identified as potential determinants of enrollment in this study.

Trial registration: Clinical Trials NCT01839708.

1. Introduction

Interventions to reduce medical costs associated with overweight and obesity [1,2] are currently limited by lack of effective strategies to address the exceptional needs of young low-income overweight and obese mothers. To have a broad public health impact on obesity, we conducted *Mothers In Motion* (*MIM),* a theory-based culturally sensitive intervention, aimed to help low-income overweight and obese young mothers prevent weight gain by promoting stress management, healthy eating, and physical activity.

Recruitment challenges have been well-documented. McDonald et al. [3] reviewed 122 trials and found that only 31% of studies reached their original recruitment target number; about 24% of studies recruited at least 80% of but less than 100% of target

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numbers. The authors also found that about 35% of studies had to reduce the intended sample size. Of studies reducing sample size, about 45% of studies reached the revised target number. Moreover, about 58% of the reviewed studies requested extensions from the funding agencies and 41% delayed the start of recruitment. Even though 75% of studies identified their study sites during the grant application stage, about 20% of studies had pre-identified sites that did not participate as planned, due to a variety of reasons, e.g., problems with funding and delays in recruitment. Foy et al. [4] evaluated the recruitment of dyspepsia management studies and found that about 43% (3/7) of such studies closed prematurely due to poor recruitment and 57% (4/7) extended their length of recruitment. Even with extended length of recruitment, only 1 trial met its target number.

Reduced enrollment rates, which is not typically reported by intervention studies may influence sample representation and study validity. In general, the enrollment rate ranges from 60% to 77% and differs by the purpose of the interventions and target populations. Reported study enrollment rates for low-income young mothers are typically around two-thirds (66% for an African American caregiver feeding and preschooler body weight intervention [5] to 68% for a birth control intervention reaching a predominantly White target audience [6]). A smoking relapse prevention program for low-income postpartum women reported enrollment rates of 60% for the intervention group and 92% for the comparison group [7]. Enrollment rates for studies of pregnant women ranged from 69% (pregnancy weight gain intervention for overweight and obese women who were predominantly White) [8] to 90% (behavioral intervention to reduce smoking, depression and violence for low-income African Americans and Latinas) [9]. Enrollment rates for middle aged adults have fallen in a similar range. For example, diabetes self-management studies showed a 59% enrollment rate for African Americans [10] and 71% for overweight and obese adults with diverse racial and ethnic backgrounds [11]. Enrollment was about 76% for a weight management program for overweight and obese adults [12] and 77% for obese adults with hypertension [13]. Factors that influence enrollment rate have not been reported by previous studies and determinants of this important aspect of program planning have been noted as nearly impossible to identify [12]. This paper describes recruitment challenges and examines the relationships among demographic characteristics and enrollment.

2. Methods

2.1. Setting and participants

Our *MIM* was conducted in partnership with The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) at the state and local levels in Michigan. WIC is a federally funded community program that provides health screening, specific nutrient-dense food benefits and nutrition consultation and makes health and community agency referrals for women who are pregnant, breastfeeding, or postpartum and for infants and young children up to age 5 years old. To be eligible to enroll in WIC, an individual must have an income at or below 185% of the federal poverty line. A detailed description of setting and study criteria has been published [14]. Briefly, participants were Non-Hispanic White or African American women who were between 18 and 39 years old, between 6 weeks and 5 years postpartum, overweight or obese (BMI 25.0–39.9 kg/m$^{2)}$, and had no self-reported type 1 or type 2 diabetes. All participants were recruited from 5 collaborating WIC agencies (10 WIC offices) in Michigan. Nearly 76% of clients in these WIC agencies had incomes at or below 130% of the federal poverty line.

2.2. Recruitment strategies, challenges, and lessons learned

Our recruitment and enrollment were about 5 months behind the initial timeline due to a delay of intervention development. Still, the project was able to enroll 634 women, which exceeded the target number (N = 525) in 28 months. We purposely oversampled participants because we planned to exclude data from women who became pregnant during the trial and a recent Michigan WIC report showed an overall increase in pregnancy rates (~5%) for our target population.

2.3. Recruitment strategies

Women coming to our collaborating WIC agencies during the data collection dates (September 2012 to January 2015) were personally invited by peer recruiters (who were themselves WIC mothers) to participate while waiting for their appointments.

The recruiters were trained to be culturally sensitive, to build rapport quickly and to relate to the potential participants. Training emphasized using a gentle and caring voice, demonstrating understanding, empathy, and excitement about the study while maintaining eye contact, and offering assistance with small tasks [15]. Recruiters explained the study purpose, confidentiality and study requirements and emphasized the *MIM*'s flexible schedule and its easy, no-cost availability. WIC mothers who were not interested in participation filled out the demographic survey. Those who were interested filled out both demographic and screening surveys based on the study criteria.

We learned from our pilot *MIM* [16] that not fully understanding the study requirements and incentives was one of the key factors leading to a high dropout rate. Therefore, we conducted cognitive interviews to develop an easy-to-read flyer (pictorial) that outlined the study's purpose, expectations, and incentives as presented in the consent form. Also, we implemented sequential screening to minimize a potential high dropout. A detailed description of sequential screening (screening I and II) has been published [14]. ***Screening I.*** Briefly, eligible participants read the flyer, then the recruiters interviewed them to assess their understanding of study requirements and their interest in participation. The recruiters would obtain consent from eligible women only if the women could demonstrate understanding of the study requirements. ***Screening II***. Consented women were required to complete a baseline phone interview before returning to their WIC office (in person) to be randomized and enrolled within 2 weeks of signing the consent form. The study procedure was approved and monitored by the Michigan State University and Michigan Department of Community Health Institutional Review Boards.

2.4. Recruitment challenges and lessons learned

Based on lessons learned from our previous pilot of *MIM* [14], we implemented numerous strategies to enhance recruitment but still experienced 6 major challenges. Below, we described these challenges and strategies recommended to minimize them. We monitored enrollment rate on a monthly basis by recruiters and study sites (WIC agencies).

2.4.1. Gaining access to study sites

When our proposal was submitted, 4 WIC agencies had agreed to collaborate with us. To increase our recruitment pool, we intended to expand the study sites from 4 to 6–7 WIC agencies, but only 1 of the 4 local WIC agencies that we contacted agreed to collaborate. When recruitment started in Year 2, 1 of the original local partner agencies had to be eliminated because of personnel change and disruptions caused by building remodeling. In Year 3,