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BRIEF REPORT

Intervention Delivery Matters: What Mothers at High Risk for Type 2 Diabetes Want in a Diabetes Prevention Program—Results from a Comparative Effectiveness Trial

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ABSTRACT

Participants in the ENCOURAGE Healthy Families Study, a family-focused, modified Diabetes Prevention Program, reported challenges to and preferences for engaging in a diabetes prevention program. Challenges with flexible intervention delivery, accessibility, the traditional group-based format, and Coronavirus Disease 2019 (COVID-19) exposure risk can be mitigated by participant preferences for one-on-one, virtual/online intervention delivery.

Trial Registration: ClinicalTrials.gov identifier, NCT01823367.

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Key Summary Points

Why carry out this study?

Current diabetes prevention programs (DPPs) struggle with engaging vulnerable, high-risk populations, such as low-income mothers with a history of gestational diabetes or prediabetes.

How can we adapt diabetes prevention programming to effectively address the needs and preferences of the most critical stakeholders—the patients while taking into consideration the current COVID-19 pandemic?

What was learned from the study?

Mothers at high risk for type 2 diabetes mellitus need flexible intervention attendance options.

Mothers at high risk for type 2 diabetes mellitus prefer one-on-one intervention sessions over the traditional group DPP format as well as virtual programming.

Virtual diabetes prevention programming is responsive to patients' needs and preferences and the COVID-19 pandemic.

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INTRODUCTION

The Diabetes Prevention Program (DPP) has been proven to be safe, effective, and sustainable across a broad range of populations, including those in vulnerable communities with the highest risk for type 2 diabetes mellitus (T2D) [1]. Unfortunately, many evidence-based risk reduction programs, such as the DPP, suffer from high attrition and low adherence due to rigid program structure [2, 3]. The recent challenges related to coronavirus disease 2019 (COVID-19) and the fear of person-to-person disease transmission [4, 5] further limits the feasibility of traditional intervention delivery. Hence, there is a pressing need to consider alternative methods to deliver diabetes interventions and to understand their effect on the most critical stakeholders, namely, patients. Therefore, in this report we present the challenges to participation and preferences for intervention delivery for women who were predominantly low-income enrolled in a modified DPP.

METHODS

The ENCOURAGE Healthy Families (ENCOURAGE) study enrolled women with at least one child (aged 8–15 years) who were overweight or obese and had histories of either gestational diabetes mellitus (GDM) and/or prediabetes. ENCOURAGE utilized a 16-week group-based DPP approach in which participants were randomized to attend weekly sessions either alone or in parallel with their children at local Young Men's Christian Association (YMCA) locations [6]. Participants were surveyed to elicit preferences for intervention delivery.

This study received approval from the Indiana University Institutional Review Board. All participants provided consent or assent. Parents consented for themselves and their participating children. Children provided assent. This study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments (ClinicalTrials.gov identifier NCT01823367).

For this report, descriptive statistics and frequencies were calculated for self-reported demographics and socioeconomic variables along with diabetes risk factors (e.g., body mass index [BMI], hemoglobin A1c [HbA1c]) and measures of intervention participation (e.g., number of sessions attended and absences). We identified questions addressing participant preferences for a diabetes prevention intervention from an exit survey administered to ENCOURAGE participants. Questions allowed multiple responses and provided an option to include other (i.e., not listed) responses. The prevalence of each response was compared (1) between completers (attended $\geq$ 8 classes) and non-completers (attended $<$ 8 classes) and (2) by intervention randomization using Fisher's exact chi-square test. Analyses were performed using SAS statistical software version 9.4 (SAS Institute, Cary, NC, USA), and statistical significance was predetermined as $p < 0.05$.

RESULTS

A total of 79 participants provided survey responses regarding their preferences and intervention engagement. Baseline characteristics are detailed in Table 1. At baseline, mean ($\pm$ standard deviation) age of the participants was 39 $\pm$ 12 years; mean BMI was 37.5 $\pm$ 6.9 (range 22.4–62.4) kg/m^2; 89.9% of participants had a BMI $>$ 30 kg/m^2); and mean HbA1c was 5.6% $\pm$ 0.3 (30.4% with HbA1C $>$ 5.7%). Participants predominantly self-identified as African American (60.8%) and European American (32.9%). There were no significant differences in baseline characteristics by intervention completion status or randomization group. Table 2 summarizes the attendance of survey respondents. Overall, half of participants did not attend intervention sessions. Only 13.5% completed the intervention. Table 3 shows that lack of time (36.4%) and scheduling conflicts (35.1%) were the most cited challenges to attendance and engagement in the intervention. The group-based format also posed a challenge, with 37.2% being unable to commit to a day/time/location that worked for others. Regarding alternative intervention delivery

Table 1 Baseline characteristics of mothers who completed the exit survey for the ENCOURAGE diabetes prevention study ($N = 79$)

Baseline characteristics	Values
Demographics	
Age (years)	39.6 ± 11.6
Ethnicity (% Hispanic or Latina)	11.4
Race (%)	
African American (Black)	60.8
European American (White)	32.9
Other	6.9
Marital status (%)	
Married	43.0
Divorced	21.5
Separated	6.33
Never married	17.7
Living with partner	7.6
Education level (%)	
High school graduate, GED credential or lower	20.5
Some college, or 2-year college degree	38.5
4-year college graduate	28.2
> 4-year college degree	12.8
Work/employment status (%)	
Employed or full-time student	84.9
Unemployed, disabled, or other	15.1
Income level (%)	
< $25,000	25.6
> $25,000 but < $35,000	15.4
> $35,000 but < $50,000	20.5
> $50,000 but < $75,000	15.4
> $75,000	16.7
Refused to answer; don't know	5.4
Number of children (%)	
1	24.7
2	33.8
3	19.5
≥ 4	22.1
Diabetes risk factors	
BMI (kg/m^2)	37.3 ± 7.8
BMI > 30 kg/m^2	89.9
Hemoglobin A1c (%)	5.7 ± 0.3
A1c > 5.7%	30.4

Values are presented as the mean ± standard deviation or as a percentage

There were no significant differences between ENCOURGAGE Study respondents and non-respondents

BMI Body mass index, *GED* General Education Development, *HbA1c* hemoglobin A1c (glycated hemoglobin)

methods and motivations, flexible attendance options (39.2%), more time and location options (31.7 and 27.9%, respectively), and ability to change attendance options (20.0%) were commonly preferred, as shown in Table 4 . At least half of the participants preferred having access to online or virtual content. Interestingly, 17.7% noted one-on-one sessions would help them stay engaged while 47.7% said being successful at weight loss would help them stay motivated.

DISCUSSION

Poor adherence and high attrition remain significant challenges for DPPs targeting persons in high-risk communities, particularly for parents with competing priorities [7]. ENCOURAGE, a youth-friendly DPP curriculum, was delivered to mothers with increased risk for T2D at local YMCAs [6]. However, like other studies, participation and engagement were met with challenges. These challenges with program participation mirror recent reports from the

Table 2 Intervention participation of mothers who completed the exit survey for the ENCOURAGE diabetes prevention study (N = 79)

Intervention participationof mothers who completed the exit survey	Values
Intervention assignment	
Mom-only group (%)	56.1
Mom and child(ren) group (%)	46.8
Attendance	
Classes attended	6.7 ± 5.4
Class absences	5.1 ± 3.4
Number of classes attended (%)	
0	50.6
1	3.8
2–4	15.2
5–7	7.6
≥ 8	13.9

Values are presented as the mean ± standard deviation or as a percentage

There were no significant differences between ENCOURGAGE Study respondents and non-respondents

Table 3 Mothers' responses to questions regarding perceived challenges to intervention attendance and engagement with comparison by intervention completion status and group randomization (N = 79)

Responses to specific questions regarding perceived challenges to intervention attendance and engagement	Percentage of those who chose response	Percentage who indicated response is/was most important
"What challenges did you face to attend the YMCA classes?[a]		
Responses related to flexibility		
Too busy/do not have enough time	36.4	24.3
Changes in my family's schedule	35.1	23.0
Demands at work	15.6	9.5
They were too time-consuming	11.4[b]	2.7
Sick kids	1.3[c]	0.0
Responses related to accessibility		
Lack of childcare	9.1	2.7
Lack of transportation	2.6[b]	2.7
Unreliable transportation	2.6[b]	2.7
Cost of transportation	3.9	0.0
Responses related to motivation		
Lacking motivation/desire to attend	16.9[c]	4.1
"What are some challenges of the group format of the YMCA classes for you and your family?"		
Responses related to flexibility		

National Diabetes Prevention Program of low retention rates for younger and racial minority populations [8]. Based on survey results, three themes emerged that can inform future delivery of diabetes prevention interventions: flexibility, accessibility, and group-based format.

The combination of scheduling conflicts and the lack of alternative program delivery modes create a perfect storm for non-engagement. The lack of flexible attendance options prevents participation in this program, especially by parents actively raising children. DPPs targeted to low-income mothers and other high-risk populations must address participant burden and opportunity costs.

Over half of participants reported wanting online or virtual sessions. The DPP has been translated into digital formats to increase

Table 3 continued

Responses to specific questions regarding perceived challenges to intervention attendance and engagement	Percentage of those who chose response	Percentage who indicated response is/was most important
I am unable to commit to a day/time/location that works for others	37.2	
Responses related to group-based delivery		
I do not like talking to/in front of people I do not know	11.4	
Sometimes I feel judged by others	7.6	
Not enough time to talk about things that are important to me	6.3	
I do not feel l can voice my personal opinion in a group	2.5	

There were no differences in response selections between mothers that were randomized to attend sessions alone versus attending sessions with parallel classes for children
YMCA Young Men's Christian Association
[a] Responses are sorted in order of most important within response theme
[b] χ^2 test indicates response was more frequently reported by intervention non-completers (< 8 sessions) than intervention completers (≥ 8 sessions), $p < 0.05$
[c] χ^2 test indicates response was more frequently reported by intervention completers (≥ 8 sessions) than intervention non-completers (< 8 sessions), $p < 0.05$

Table 4 Mothers' responses to questions regarding preferred alternative intervention delivery methods and motivations with comparison by intervention completion status and group randomization ($N = 79$)

Mothers' responses to questions regarding preferred alternative intervention delivery methods and motivations	% who chose response
"Are there other ways of delivering the YMCA classes that would be easier for your family to attend?"[a]	
Responses related to flexibility	
Flexible attendance options (ability to go to different locations, days, or times on a drop-in basis)	39.2
More program time options	31.7[b]
Having more location options (church, school, housing complex, community center, library, grocery/drug store, etc.)	27.9
Responses Related To Accessibility	
Online/web-based sessions	31.6
Video/virtual sessions with a coach (Skype, FaceTime, etc.)	20.3
Text message/email alerts	13.9
Video/DVD package for classes	12.7
Phone based	7.6
Responses related to group-based delivery	
One-on-One	17.7
"What would motivate you to attend the YMCA classes regularly even when your schedule made it challenging to do so?"	
Responses related to flexibility	
Ability to alter/change up location or day/time	20.0[b]
Responses related to group-based delivery	
Getting a motivating message/hearing from one of my group members	5.3[b]

Table 4 continued

Mothers' responses to questions regarding preferred alternative intervention delivery methods and motivations	% who chose response
Hearing about the successes of my group	5.3
Responses related to motivation	
Being successful at weight loss	47.7[b]
Getting a motivating message/hearing from my coach/leader	16.0
Recognition/incentives for accomplishments (attendance, reaching goals, etc.)	6.7

There were no differences in response selections between mothers that were randomized to attend sessions alone versus attending sessions with parallel classes for children

[a] Responses are sorted in order of most important within response theme

[b] χ^2 test indicates response was more frequently reported by intervention non-completers (< 8 sessions) than intervention completers (≥ 8 sessions), $p < 0.05$

accessibility and cost-effectiveness [9–11]. However, the dissemination of such formats has been limited for those who may benefit most from DPP interventions due to persistent beliefs that low-income Americans have limited access to technology (e.g., computers, internet, and smartphones).

The ENCOURAGE intervention was delivered in a group setting, to allow for an economy of time and resources, as well as to facilitate the sharing of knowledge and points of view of fellow participants. However, women reported a preference for one-on-one sessions. One-on-one sessions could mitigate participants' feeling uncomfortable or judged. Also, one-on-one sessions would resolve scheduling issues of a group-based model. A recent pilot study of veterans with prediabetes who attended individualized lifestyle counseling sessions delivered one-on-one by medical providers showed promising results in reducing A1c levels [12].

It is important to note a few limitations of the current study, including low engagement and low intervention completion rate. The survey response rate was 61.7%, potentially resulting in selection bias. However, there were no significant differences in baseline characteristics between respondents and non-respondents. Also, the survey was developed for this study and was not validated, which could introduce response bias due to measurement error. While the results may not be generalizable, they do provide practical implications for diabetes prevention programming in "real-world" settings.

In light of the current COVID-19 pandemic, consideration must be given to minimizing risk of exposure for those with and at high risk for T2D. Offering one-on-one, online/virtual programming not only addresses the preferences for tailored engagement, but also reduces risk of exposure for both participants and DPP staff. Online/virtual delivery of family-based diabetes prevention interventions can expand access while also addressing preference for one-on-one sessions and the need for flexible attendance options.

CONCLUSION

In conclusion, the demands required for participation in evidence-based diabetes prevention interventions in socioeconomically vulnerable populations, youth, and families are prohibitively high and limit the effectiveness of these programs in the community. Lower personal demands for participation in programs and flexible program attendance options designed to prevent diabetes will be required.

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Compliance with Ethics Guidelines. This study received approval from the Indiana University Institutional Review Board. All participants provided consent or assent. Parents consented for themselves and their participating children. Children provided assent. This study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments (ClinicalTrials.gov identifier NCT01823367).

Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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