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A web-based pedometer program in women with recent histories of gestational diabetes

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Abstract

Aims—Women with remote histories of gestational diabetes mellitus (GDM) can reduce their diabetes risk through lifestyle changes, but the effectiveness of interventions in women with more recent histories of GDM has not been reported. Therefore, we conducted a pilot study of a low-intensity web-based pedometer program targeting glucose intolerance among women with recent GDM.

Methods—Women with a GDM delivery within the past 3 years were randomized to a 13-week intervention consisting of a structured web-based pedometer program which gave personalized steps-per-week goals, pedometers, and education regarding lifestyle modification vs. a letter about diabetes risk reduction and screening after delivery for GDM (control condition). The main outcome measures were change in fasting plasma glucose (FPG) and 2-hour glucose levels on a 75-gram oral glucose tolerance test (OGTT) between baseline and 13-week follow-up. Weight was a secondary outcome and behavioural constructs (self-efficacy, social support, risk perception) were also assessed.

Results—Forty-nine women were enrolled. At 13 week follow-up, women randomized to the intervention did not have significant changes in behavioural constructs, physical activity, or anthropometrics compared to women in the control group. Changes in FPG (–0.046 mmol/l vs. 0.038 mmol/l, $p=0.65$), 2-hour glucose values (–0.48 mmol/l vs. –0.42 mmol/l, $p=0.91$) and weight (–0.14 kg vs. –1.5 kg, $p=0.13$) were similar between the control and intervention groups, respectively.

Conclusions—Structured web-based education utilizing pedometers is feasible although uptake may be low. Such programs may need to be supplemented with additional measures in order to be effective for reduction of diabetes risk.

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Keywords

gestational diabetes; pedometers; physical activity; internet; intervention

Introduction

Interventions to improve lifestyle have been shown to reduce diabetes risk among adults with glucose intolerance, including women with remote histories of gestational diabetes mellitus (GDM).[1] To date, no reports examine whether such interventions can improve glucose levels among women with more recent histories of GDM. Lifestyle changes may be difficult to implement in this population; women with recent GDM cite multiple barriers to lifestyle change, including low perception of risk,[2] caregiving for young children, and fatigue.[3]

Pedometer programs, particularly those which offer individualized goals, reduce post-challenge glucose levels among adults with impaired glucose tolerance.[4] Such programs have not been attempted in newly postpartum women, but focus group work has suggested that flexible programs that address the issues specific to women with young children might address barriers to behaviour change.[5] Therefore, the aim of this pilot study was to examine the feasibility of such a program and its impact upon behavioural constructs such as self-efficacy, behaviours such as physical activity, anthropometrics, and insulin and glucose levels.

Patients and Methods

Participants

Potential participants were recruited from a university health system, a large non-profit managed care plan, and several private practices in southeastern Michigan through a combination of targeted mailings and directed referrals from providers (Figure 1). Recipients of targeted mailings had an administrative discharge code (648.8) consistent with a GDM pregnancy within the past 3 years. The 1-page mailings contained the study website address, information regarding GDM and diabetes risk and recommendations regarding lifestyle modification. On the website, women were asked to confirm their GDM diagnosis within the past 3 years, lack of a current diagnosis of diabetes or pregnancy, age > 18 years, < 150 minutes of self-reported physical activity per week and ability to walk, fluency in English, and a working e-mail address and Windows XP or Vista platform. If eligible by the web-based screen, women were then contacted by e-mail and telephone to arrange a baseline face-to-face visit and to confirm that they were at least 6 weeks postpartum. Women were required to have clearance from their medical provider confirming that they had a GDM pregnancy within the past 3 years and had no contraindications to participation.

At the baseline visit, women underwent anthropometric testing by study staff blinded to randomization assignment, along with 75-gram oral glucose tolerance testing (OGTT) and urine pregnancy testing. Women were excluded from the randomized trial if they had a positive pregnancy test, a fasting glucose value of > 7 mmol/l, a 2-hour glucose value > 11.0

mmol/l, or reported current met formin or oral glucocorticoid use. Women were also asked to fill out a baseline on-line survey enquiring after medical history and behavioural constructs including self-efficacy for physical activity [6] and weight management,[7] as well as perception of risk.[8] At the conclusion of the intervention at 13 weeks, women were asked to undergo repeat anthropometric testing, OGTT, and on-line surveys, and to rate satisfaction with the intervention. For each visit, women received \$60 to help defray costs of transportation, parking and childcare. Study procedures were approved by the University of Michigan Institutional Review Board.

Randomization was automated and determined by a randomly generated number sequence. Women assigned to the control arm were not given any additional materials or information, but at study conclusion received a pedometer and a free subscription to a commercially available web-based walking program.

Women assigned to the intervention received a 13-week program that provided web-based education, pedometer messaging, and an internet forum (on-line Appendix).[9]The intervention curriculum targeted the following domains: perception of diabetes risk, self-efficacy for weight and physical activity, benefits of and barriers to lifestyle change (particularly incorporating tips for mothers with young children), and self-regulatory strategies. The curriculum was displayed on the website and messages changed daily. Women received a study pedometer and instructions to upload weekly to a computer program, which in turn translated pedometer data into individualized step-count goals and progress made towards these goals. This information was delivered through each woman's personal study web page and via e-mail. Feedback about progress toward goals was displayed graphically and via text messages. All graphs displayed total steps; success or failure in achieving goals was based only on total step counts. Women received credit for any and all walking during the day. Goals were not necessarily monotonically increasing; if a woman had low step counts for one week, the subsequent week's goals would be lower than the goal for the previous week. The maximum allowable goal was 10,000 steps per day. Women were also able to access an on-line message board that allows study participants to interact with each other with a pseudonym.

The main outcome measures were the change in glucose levels between baseline and follow-up, between control and intervention women. Change in weight between study arms was a secondary outcome. Due to the pilot nature of this investigation, we also examined changes in purported mediators such as self-efficacy, risk perception, and physical activity levels. The Michigan Diabetes Research and Training Center Chemistry core performed glucose assays. Glucose assays used the Cobas Mira Chemistry Analyzer from Roche Diagnostics Corporation, Indianapolis, Indiana, United States of America. Intra-assay variabilities are 2% at both 4.6 and 15.7 mmol/l. Inter-assay variabilities are 2.9% at 4.6 mmol/l and 2.6% at 15.4 mmol/l. Insulin was measured using a double-antibody radioimmunoassay with a ¹²⁵I-Human insulin tracer (Linco Research). Limit of sensitivity for the assay is 14.6 pmol/l, and inter-assay and intra-assay variabilities are 3.4% and 2.7% respectively at 174 pmol/l.

Comparisons between control and intervention women at baseline, at follow-up, and change in outcomes between baseline and 13 weeks were conducted using chi-square tests and t-test

procedures. All tests were 2-sided. All analyses were conducted using STATA 11.0 (College Station, TX).

Results

The study recruitment and flow diagram is illustrated in Figure 1. Of the 3285 recruitment mailings and 13 direct referrals from providers, 49 women (49/3298 or 1.5%) were eventually randomized. Specifically, 224 women who received information regarding the intervention chose to access the website (224/3298 or 6.8%). Of these 224 women, 150 (67%) were eligible at this stage; of note, 6 women already reported having been diagnosed with diabetes and/or being currently pregnant. Of the 150 eligible women, only 55 chose to attend the baseline visit, with the majority of women not citing a specific reason for participating. For the majority of women who received information regarding the intervention, we do not have their reasons for not participating. Of the 74 women for whom we have specific information for not proceeding (those women who chose to take the web-site screening tool), the most common reason for not proceeding was that they were not sedentary.

Characteristics of women by randomization arm are illustrated in Table 1, along with baseline measures for demographics, behavioural constructs, behaviours, anthropometrics, insulin, and glucose. There were no significant differences between randomization arms in any of the measured variables at baseline. The population participating was, in general, well-educated and affluent and primarily non-Hispanic white. The majority of women were overweight or obese.

Table 1 notes baseline and follow-up measures for potential mediators of glucose tolerance. In summary, no significant changes from baseline to follow-up were noted in the behavioural constructs or behaviours, particularly physical activity, between study arms. Compared to the control arm, women in the intervention arm had slightly greater declines in weight and insulin resistance, but differences from the control arm were not statistically significant. No changes in point estimates were observed in either fasting or 2-hour glucose.

In the intervention group, women uploaded an average number of 1.6 ± 0.64 times per week. Only 3 women posted on the forum, and these posts were directed at the study team, rather than to other participants. Upon conclusion of their participation, women randomized to the intervention arm noted that they were satisfied with the intervention, while acknowledging that they were not able to institute the activity changes and other recommended behaviours.

Discussion

Women with recent GDM have a seven-fold increase in risk for diabetes,[10] but no reports address risk reduction in this population. Internet interventions have the potential for low cost and high-efficacy, particularly for interventions which involve large populations.[11, 12]In a pilot-test of this program, we found that out of a large potential candidate population, relatively few women who received information about the intervention proceeded to access the website to learn more about the intervention. Of women who did access the website to read about the study, relatively few proceeded to enrollment. We also

found that the program had minimal impact upon behavioural constructs, behaviours, or glucose. While favorable trends were observed in weight and insulin levels, differences between arms did not reach the level of statistical significance.

Although explanations are speculative, we may have observed low enrollment rates for several reasons. Internet access may have been a barrier, particularly since women with GDM tend to have lower socioeconomic status than women without GDM.[13] However, the candidate population for our study had access to care and was insured, and thus may have been more likely to have internet access than other disadvantaged groups. The requirement for a face-to-face visit at baseline and at follow-up, which in turn entailed anthropometrics and OGTTs, may have also decreased interest. However, the most commonly cited reason for not participating was that women perceived that they were actually physically active, and thus an intervention aimed primarily at physical activity could have been less appealing.

Tate et al found that participants in an internet-based weight loss intervention could achieve weight loss with weekly behavioural weight loss lessons, self-monitoring diaries with individualized therapist feedback, and an on-line forum,[14] Yates et al found that individualized pedometer feedback could reduce post-challenge glucose levels although changes in weight and fasting glucose were not achieved.[4] Neither of these studies focused upon women with recent GDM. Our intervention included individualized pedometer feedback but did not include therapist contact or diaries, and it may be that regular contact with an interventionist or more intensive self-monitoring, via the internet or other media, is also needed to change behavior. Although we expected that these mothers would be more frequent posters to the internet support page than has been previously observed, few women posted to the internet forum, consistent with prior research that over 250 participants are optimal to maintain an active on-line community.[15, 16] As our study was a pilot study and enrolled a small number of participants, it may be that we would have seen more significant differences in a larger sample. However, the magnitude of change in glucose was extremely small and suggests that the program was lacking in effectiveness, rather than the pilot lacking adequate sample size. In addition, changes in the point estimates of key mediators, such as physical activity, were not observed. Based on the mean changes and standard deviations in glucose observed in this pilot study, and assuming that rates of eligibility and uptake were similar to the pilot study, a larger study would have required a recruitment sample exceeding 6,000 women to detect a significant change in 2-hour glucose between groups.

In conclusion, this pilot test of a pedometer program demonstrates that structured education via internet had small impact upon weight and insulin and minimal impact on behaviors in women with recent GDM. Moreover, although we demonstrated feasibility, uptake of the intervention was relatively low, which would make dissemination less cost-effective. Supplementing internet interventions with more traditional methods of delivery, such as individualized counseling, with a greater emphasis upon nutritional intake and weight loss, may be more effective and cost-effective.

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Abbreviations

DPP	Diabetes Prevention Program
GDM	gestational diabetes mellitus
OGTT	oral glucose tolerance test
PEG	pedometers for gestational diabetes

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Figure 1.
Study Flow Diagram.

Table 1

Characteristics of participants at baseline and changes between baseline and follow-up for behavioural constructs, behaviours, anthropometrics, insulin, and glucose. Means $\pm$ standard deviations shown.

	<u>Control</u>	<u>Intervention</u>	<u>p-value</u>
Behavioural constructs			
Baseline risk perception for diabetes (%)			0.50
Almost no chance of diabetes	4	5	
Slight chance of diabetes	29	14	
Moderate chance of diabetes	43	38	
High chance of diabetes	25	43	
Follow-up risk perception for diabetes (%)			0.56
Almost no chance of diabetes	13	11	
Slight chance of diabetes	35	26	
Moderate chance of diabetes	35	26	
High chance of diabetes	17	37	
Any social support for physical activity at baseline (%)	64	67	0.86
Any social support for physical activity at follow-up (%)	74	84	0.42
Self-efficacy for weight at baseline (range 20–100)*	68.9 $\pm$ 11.4	73.0 $\pm$ 11.5	0.23
Change in self-efficacy for weight from baseline to follow-up [†]	−0.39 $\pm$ 10.0	2.4 $\pm$ 7.7	0.33
Self-efficacy for physical activity at baseline (range 7–49)*	21.7 $\pm$ 8.1	22.4 $\pm$ 6.5	0.74
Change in self-efficacy for activity from baseline to follow-up [†]	3.2 $\pm$ 7.1	1.8 $\pm$ 4.8	0.47
Behaviours			
Any physical activity (minutes/week) at baseline (%)			0.61
0	4	0	
Some, but < 60	57	52	
$\geq$ 60	39	48	
Any physical activity (minutes/week) at follow-up (%)			0.25
0	4	5	
Some, but < 60	39	16	
$\geq$ 60	57	79	
Mild physical activity (minutes/week) at baseline (%)			0.26
0	43	29	
Some, but < 60	43	38	
$\geq$ 60	14	33	
Mild physical activity (minutes/week) at follow-up (%)			0.20
0	35	58	
Some, but < 60	39	16	
$\geq$ 60	26	26	
Moderate physical activity (minutes/week) at baseline (%)			0.81
0	50	57	
Some, but < 60	32	24	
$\geq$ 60	18	19	

	Control	Intervention	p-value
Moderate physical activity (minutes/week) at follow-up (%)			0.51
0	52	42	
Some, but < 60	17	11	
>= 60	30	47	
Vigorous physical activity (minutes/week) at baseline (%)			0.81
0	50	57	
Some, but < 60	32	24	
>= 60	18	19	
Vigorous physical activity (minutes/week) at follow-up (%)			0.65
0	87	89	
Some, but < 60	4	0	
>= 60	9	11	
Baseline pedometer steps/week (intervention group only)		5076 ± 1321	
Follow-up pedometer steps/week (intervention group only)		543 ± 2074	
Anthropometrics			
Baseline weight (kg)	82.1 ± 20.1	80.8 ± 18.8	0.81
Change in weight from baseline to follow-up (kg)	-0.14 ± 2.2	-1.5 ± 3.4	0.13
Baseline body mass index (BMI) (kg/m ²)	30.5 ± 7.5	29.8 ± 6.8	0.74
Change in BMI from baseline to follow-up (kg/m ²)	-0.07 ± 0.82	-0.53 ± 1.3	0.16
Baseline waist circumference (cm)	93 ± 14	93 ± 17	0.88
Change in circumference from baseline to follow-up (cm)	1.3 ± 6.7	0.33 ± 5.2	0.62
Insulin and glucose measures			
Log fasting insulin	2.8 ± 0.44	3.1 ± 0.76	0.1
Change in log fasting insulin	0.03 ± 0.38	-0.16 ± 0.40	0.18
Fasting plasma glucose (mmol/l)	5.1 ± 0.7	5.1 ± 0.5	0.95
Change in fasting plasma glucose (mmol/l)	-0.046 ± 0.57	0.038 ± 0.62	0.65
2-hour glucose (mmol/l)	7.0 ± 2.0	6.8 ± 1.9	0.66
Change in 2-hour glucose (mmol/l)	-0.48 ± 1.6	-0.42 ± 1.8	0.91

* Higher scores indicate greater self-efficacy

[†] Positive scores indicate an increase in self-efficacy